UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

IN RE ATHENEX, INC. SECURITIES LITIGATION This Document Relates To: All Actions.	No. 21-cv-337 **PLAINTIFF'S AMENDED CLASS ACTION COMPLAINT** JURY TRIAL DEMANDED

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Court-appointed Lead Plaintiff, John McKenzie, by and through his undersigned counsel, brings this action under the Securities Exchange Act of 1934 (the "Exchange Act") on behalf of himself and a class of other similarly situated investors against Athenex, Inc. ("Athenex" or the "Company") and other Defendants named herein. Plaintiff alleges the following based upon personal knowledge as to himself and his own acts, and upon information and belief as to all other matters. Plaintiff's information and belief is based on the ongoing investigation of his undersigned counsel, which includes review of Defendants' press releases, conference call transcripts, filings with the United States Securities and Exchange Commission ("SEC"), and other public statements; news stories, analyst reports, and other public information concerning Athenex and the industry within which it operates; and interviews with former Athenex employees and/or others familiar with the Company.

I. NATURE OF THE ACTION

1. This securities class action is brought on behalf of a class (the "Class") consisting of all persons or entities other than Defendants and their affiliated persons who purchased or otherwise acquired Athenex common stock between August 7, 2019 and February 26, 2021, inclusive (the "Class Period"). Plaintiff brings claims against Athenex and certain of its current and former officers and directors (collectively, "Defendants"). The claims arise under §§10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder.

2. Athenex is a clinical stage biopharmaceutical company working to develop and commercialize new cancer treatments. During the relevant period, the Company's prospects were largely dependent on obtaining U.S. Food and Drug Administration ("FDA") approval of "Oraxol" (a/k/a "Oral Paclitaxel"), a proposed treatment for metastatic breast cancer ("mBC"). Oraxol combines paclitaxel, a type of chemotherapy, with encequidar, an inhibitor of P-glycoprotein ("PGP"), a protein found in the gastrointestinal tract. PGP inhibits the oral absorption of a large

number of drugs including clinically proven and widely used chemotherapy drugs such as paclitaxel, thus restricting their current dosing to IV administration. However, IV administration of paclitaxel frequently results in adverse side effects due, in part, to high peak blood concentration levels and the use of solubilizing agents to facilitate IV administration. IV paclitaxel's most serious side effects are a significant drop in white blood cells ("neutropenia") and damage to the peripheral nervous system ("neuropathy"). Oraxol was designed to facilitate oral absorption of paclitaxel thereby overcoming the challenges of IV administration and leading to better tolerability and outcomes. Moreover, oral administration of paclitaxel offered the added benefit of ease of use allowing patients to avoid travel to a hospital or infusion center for intravenous administration of paclitaxel by a healthcare professional. With a metastatic cancer market that the Company estimated to be as large as $20 billion, the possibility of a successful Phase 3 trial of Oraxol fueled investor interest and the Company's stock price.

3. Between December 2, 2015 and July 25, 2019, Athenex conducted a Phase 3 trial (the "Phase 3 Trial" or "Trial") that was required to obtain FDA approval of Oraxol for treatment of patients with metastatic breast cancer. Starting on August 7, 2019, shortly after the Trial's completion, Defendants began issuing a series of false and misleading statements touting the prospects for obtaining FDA approval of Oraxol for treatment of metastatic breast cancer based on the results of the Phase 3 Trial. For example, on an earnings call on August 7, 2019, Athenex's Chief Executive Office ("CEO"), Defendant Johnson Y.N. Lau ("Lau"), touted the Trial's success and declared its "successful outcome" to be "a potentially transformative event for Athenex."

4. In a press release issued the same day, the Company asserted that the major goals of the Trial had been met. Specifically, Defendants claimed that Oraxol showed a statistically significant improvement compared to IV paclitaxel on the primary efficacy endpoint, with 36% of patients administered Oraxol experiencing a shrinkage in tumor size, compared with 24% of

patients administered IV paclitaxel. In addition, the release claimed that "the results showed that the proportion of confirmed responders with a duration response of more than 150 days was 2.5 times higher in the Oral Paclitaxel group than in the IV paclitaxel group." Further, the release reported that "[b]ased on the data cut-off on July 25, 2019, there was a strong trend in progression-free survival . . . and . . . in overall survival . . . favoring Oral Paclitaxel compared with IV paclitaxel." Based on the results, the release quoted Athenex's Chief Medical Officer ("CMO") Defendant Rudolf Kwan ("Kwan") as stating that Athenex would "be preparing [its New Drug Application seeking FDA approval] as soon as possible."

5. Thereafter, for the next year and a half, Defendants issued numerous statements, claiming that the NDA was "on track," presented "strong clinical data," that the Company was "putting all the key elements in place for successful oral paclitaxel launch," and that Oraxol had the "potential[] [to] become the chemotherapy of choice in metastatic breast cancer."

6. However, contrary to Defendants' numerous claims, and as Defendants knew or recklessly disregarded, there were significant, undisclosed flaws in the Phase 3 Trial that created substantial known, but undisclosed, risks to obtaining FDA approval, which were well-known within the Company but not disclosed to the public.

7. ***First***, Defendants knew or recklessly disregarded that Athenex's decision to use the abbreviated §505(b)(2) pathway in seeking approval of Oraxol's NDA without obtaining the FDA's prior authorization created a substantial risk that the NDA would be rejected or that an additional clinical trial would be required. Section 505(b)(2) of the Food Drug and Cosmetic Act ("FDC Act") provides an abbreviated approval pathway for certain new drug applications that rely on data not developed by the applicant. The provisions of §505(b)(2) were created, in part, to help avoid unnecessary duplication of studies already performed on a previously approved ("reference" or "listed") drug. While one of Oraxol's ingredients – paclitaxel – was an FDA-approved treatment

for metastatic breast cancer, Oraxol's other ingredient – encequidar – had not been previously approved by the FDA. A recent study of 226 NDAs submitted pursuant to §505(b)(2) that were approved in the five-year period from 2012 to 2016 found that FDA classification types 1 and 2 (new molecular entities and new active ingredients, respectively) were rare because such products would typically be submitted as §505(b)(1) NDAs.[1] Personnel in Athenex's internal regulatory affairs division and outside regulatory consultants for the Company repeatedly questioned whether §505(b)(2) was the appropriate pathway for Oraxol's NDA and advised Athenex's management to seek the FDA's approval to use this abbreviated pathway before submitting the NDA or risk having the FDA require another clinical trial before it approved the NDA for Oraxol.

8. ***Second***, two Confidential Witnesses who worked on the Company's submissions to the FDA in connection with its efforts to obtain FDA approval for Oraxol – a former Athenex employee in its regulatory division and a regulatory consultant – indicated that the NDA's approval was at significant risk due to multiple undisclosed changes during the Phase 3 Trial to the Chemistry, Manufacturing, and Controls ("CMC") practices used to manufacture Oraxol. These major changes, which included selection of different manufacturing sites, scale of production, and changes to manufacturing processes, made NDA approval unlikely because these changes disrupted the "comparability" of the data submitted in Oraxol's earlier Phase 1 and 2 studies and the Phase 3 study. Each of these CWs reported that Athenex was aware of and failed to address these issues, by, for example, adequately studying the "bioequivalence" between past and present CMC practices. In fact, CW2, a former Senior Regulatory Staffer, attended and made presentations at multiple meetings with Athenex's senior leadership, including Defendant Kwan,

[1] Ingrid Freije, *et al*., *Review of Drugs Approved via the 505(b)(2) Pathway: Uncovering Drug Development Trends and Regulatory Requirements*, DIA THERAPEUTIC INNOVATION & REGULATORY SCIENCE (Oct. 12, 2018), https://journals.sagepub.com/doi/pdf/10.1177/216847901 8811889.

during which the likelihood that Oraxol's NDA would not be approved – including on these grounds – was presented and discussed.

9. ***Third***, Defendants knew or recklessly disregarded serious undisclosed risks that the Phase 3 Trial had not been conducted free from "biased observation" as required by 21 C.F.R. §314.126. The Trial's primary determinant of efficacy – Objective Response Rate ("ORR") – measured the tumor size reduction in patients administered Oraxol and IV paclitaxel. One method of reviewing data and eliminating or reducing bias is through the use of a Blinded Independent Central Review ("BICR"), a third party that reviews clinical data and makes assessments. Athenex utilized Intrinsic Imaging LLC ("Intrinsic" or "the BICR"), a Massachusetts-based laboratory, as its BICR. However according to CW1, a former Clinical Research Associate at Athenex who worked exclusively on the Phase 3 Trial, many conversations pertaining to trial protocol discrepancies (*e.g.*, the size of tumors and whether a patient qualified to remain in the Phase 3 Trial) occurred between doctors at the trial sites, who were unblinded to the data, and the BICR firm, which was supposed to be "blinded," which had the potential to introduce bias into the review process and risked undermining the certainty and reliability of the Trial's data.

10. ***Fourth***, Defendants knew or recklessly disregarded that the Company's decision to conduct the Phase 3 Trial entirely outside of the United States created significant risk to gaining FDA approval given the FDC Act's stringent requirements for foreign clinical data, codified at 21 C.F.R. §314.106(b). That section requires NDA applicants to properly demonstrate that "[t]he foreign data [submitted] are applicable to the U.S. population and U.S. medical practice," and states that "[f]ailure of an application to meet any of these criteria will result in the application not being approvable based on the foreign data alone." CW2 stated that the potential that the FDA would recommend a new clinical trial of patients representative of the population in the U.S. was something that had been widely discussed at Athenex.

11. Despite Defendants' full knowledge (or at best, reckless disregard) of the Phase 3 Trial's serious shortcomings – each one of which alone provided the FDA sufficient grounds to deny or significantly delay approval of the Oraxol NDA – throughout the Class Period, Defendants repeatedly touted the Trial's supposed success and the high likelihood of NDA approval.

12. The risk that the NDA would not be approved materialized on Monday, March 1, 2021, when the Company issued a press release before the market opened stating that it had received a complete response letter ("CRL") from the FDA indicating that Oraxol's "application [was] not ready for approval in its present form." Although the CRL itself was not released,[2] the press release indicated that the CRL gave the following reasons for the FDA's decision: (i) "[t]he FDA . . . expressed concerns regarding the uncertainty over the results of the primary endpoint of objective response rate (ORR) at week 19 conducted by blinded independent central review (BICR)" noting that "the BICR reconciliation and re-read process may have introduced unmeasured bias and influence on the BICR;" (ii) the FDA "recommended that Athenex conduct a new[,] adequate[,] and well-conducted clinical trial in a patient population with metastatic breast cancer representative of the population in the U.S.;" and (iii) the FDA indicated its concern of safety risk to patients in terms of an increase in neutropenia-related sequelae on the Oral Paclitaxel arm compared with the IV paclitaxel arm."

13. The market reacted swiftly and negatively to the disclosures. Athenex's share price plummeted from its Friday, February 26, 2021 closing price of $12.10 per share to a Monday, March 1, 2021 close of just $5.46 per share, on volume of approximately 48 million shares. This represents a one-day drop of approximately 55% and a loss of $620 million in the Company's market capitalization.

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[2] The FDA has not publicly released the CRL, as federal regulations, codified at 21 C.F.R. §20.61, generally prohibit the release of CRLs prior to a final determination (*i.e.*, either approval or denial).

14. On October 11, 2021, Athenex announced that after meeting with the FDA "to review with the FDA a proposed design for a new clinical trial intended to address the deficiencies raised in the [CRL] . . . and discuss the potential regulatory path forward for Oral Paclitaxel in mBC in the U.S.," Athenex had determined not to perform another Phase 3 clinical trial, thereby abandoning its efforts to obtain FDA approval of Oraxol as a treatment for metastatic breast cancer in the U.S.[3] As of the filing of this Amended Complaint, Athenex's stock price is $1.91, which amounts to a further 65% drop from the already low $5.46 of March 1, 2021.

15. By this action, Plaintiff now seeks a recovery for himself, and the Class he seeks to represent, for the massive losses they have suffered as a result of Defendants' fraudulent and deceptive conduct.

II. JURISDICTION AND VENUE

16. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5).

17. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1331.

18. Venue is proper pursuant to 15 U.S.C. §78aa and 28 U.S.C. §1391(b) and (c).

19. At all relevant times, Athenex was headquartered and conducted business in this District at 1001 Main Street, Suite 600, Buffalo, New York. In addition, many of the acts charged herein, including the preparation and dissemination of materially false and misleading information, occurred in substantial part in this District.

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[3] Athenex, Inc., Current Report (Form 8-K) (Oct. 11, 2021).

20. In connection with the acts alleged herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the U.S. mail, interstate telephone communications, and the facilities of a national securities exchanges.

III. PARTIES

A. Plaintiff

21. Lead Plaintiff John McKenzie ("McKenzie" or "Plaintiff"), as set forth in his certification previously filed with the Court, purchased Athenex common stock during the Class Period and was damaged by Defendants' conduct as alleged herein.

B. Defendant Athenex

22. Defendant Athenex, Inc., is a clinical stage biopharmaceutical company working to develop and commercialize new cancer treatments. One of the Company's main drug candidates is "oral paclitaxel and encequidar" (*i.e.*, "Oral Paclitaxel" or "Oraxol") for the treatment of metastatic breast cancer. Incorporated in Delaware, Athenex's headquarters are in Buffalo, New York. Shares of Athenex are listed on the NASDAQ Global Select Market ("Nasdaq") under the ticker "ATNX."

C. The Individual Defendants

23. Defendant Johnson Y.N. Lau ("Lau") has served as the Company's Chief Executive Officer ("CEO") since 2011 and the Chairman of the Company's Board of Directors since 2003. Defendant Lau personally made numerous of the materially false and misleading statements at issue herein.

24. Defendant Jeffrey Yordon ("Yordon") has served as Athenex's Chief Operating Officer ("COO") since April 2016 and President of Athenex's Pharmaceutical Division since February 2017. Defendant Yordon personally made multiple of the materially false and misleading statements at issue herein.

25. Defendant Rudolf Kwan ("Kwan") has served as the Company's Chief Medical Officer ("CMO") since 2014. Defendant Kwan personally made numerous of the materially false and misleading statements at issue herein.

26. Defendant Timothy Cook ("Cook") has served as the Company's Senior Vice President ("SVP") of Global Oncology since July 2018. Defendant Cook personally made multiple of the materially false and misleading statements at issue herein.

27. The Defendants named in ¶¶23-26 are collectively referred to herein as the "Individual Defendants." The Individual Defendants, by virtue of their positions with the Company, possessed the power and authority to control the contents of the Company's SEC filings, public statements, and presentations to securities analysts, investors, and other market participants. Each Individual Defendant was provided with copies of the Company's statements and public filings alleged herein to be materially false or misleading prior to, or shortly after, their issuance, and each had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information, each of these Defendants knew that the material adverse facts specified herein had not been disclosed to, and were being concealed from, the investing public, and that the positive representations which were being made were materially false and/or misleading when made. Each Individual Defendant is liable for the false statements pleaded herein, as those statements were each "group-published" information and the result of the collective actions of these Defendants pursuant to a common scheme and wrongful course of conduct.

IV. SUBSTANTIVE ALLEGATIONS

A. Background

28. Athenex is a global biopharmaceutical company principally concerned with the discovery, development, and commercialization of drugs for the treatment of cancer. The

Company is organized around three platforms: (i) an Oncology Platform, dedicated to the research and development of Athenex's proprietary drugs and chemical compounds such as Oraxol; (ii) a Global Supply Chain Platform, focused on contract manufacturing, microbiological and analytical testing, and the production and sale of active pharmaceutical ingredients; and (iii) a Commercial Platform, aimed at the manufacturing and sale of generic pharmaceutical products. During the relevant period, the Company's fortunes were dependent on development of its Orascovery technology, which is based on the novel PGP pump inhibitor molecule, encequidar. According to the Company, oral administration of encequidar in combination with established chemotherapy agents such as paclitaxel had been shown in its clinical studies to improve the absorption of these agents by blocking the PGP in the intestinal wall. Oral paclitaxel and encequidar, known as "Oraxol" or "Oral Paclitaxel," a potential drug for treatment of metastatic breast cancer, was the lead asset in Athenex's Oncology Platform.

29. Athenex had licensed Oraxol from Hanmi, a South Korean pharmaceutical company, in December 2011 for an immediate payment of $250,000 in addition to future milestone and royalty payments. In the years since it acquired the drug, Athenex has conducted several Phase 1 and 2 studies with Oraxol testing it on mBC patients, as well as other forms of cancer, including angiosarcoma.

30. In June of 2017, while the Phase 3 Trial of Oraxol was ongoing, Athenex went public, selling 6.9 million shares of common stock at $11 per share and raising approximately $64 million in an initial public offering ("IPO"), to fund operations, including the continued development of Oraxol.

31. Just ***seven months*** after its IPO, on January 25, 2018, Athenex was forced to raise another roughly $68 million by selling a further 4.765 million shares at $15.25 per share in a secondary offering ("SPO"). On September 10, 2020, shortly after the conclusion of the Phase 3

Trial for Oraxol, the Company again was forced to sell shares to the public, raising another $126.5 million.

32. Notwithstanding its capital raising efforts, Athenex has significant liabilities. As of the end of FY 2020, Athenex's long-term debt stood at almost $150 million and its total liabilities were approximately $220 million, an astonishing burden for a company its size.

33. With approximately 70,000 metastatic breast cancer patients diagnosed in the United States each year, and the potential to repurpose Oraxol for the hundreds of thousands of patients diagnosed with other types of metastatic cancers each year, the potential for FDA approval of Oraxol for treatment of metastatic breast cancer fueled investor interest in Athenex and its stock price.

B. Oraxol Explained

34. Oraxol is a drug in capsule form that delivers the chemotherapeutic agent "paclitaxel," which may prove effective in merging with cancer cells and blocking their ability to divide, stopping the cancer's growth. Initially identified in the early 1970s as a potential cancer-fighting drug, multiple companies have had some success in deploying paclitaxel, including the Bristol-Myers Squibb Company, which in 1992 developed injectable and intravenous paclitaxel regimens to treat ovarian, breast, and lung cancer, which the FDA approved in 1994 (*i.e.*, IV paclitaxel), and Celgene Corporation, a Bristol-Myers Squibb subsidiary, which received permission from the FDA in 2005 to market an intravenous variant of IV paclitaxel, named "Abraxane".

35. However, IV administration of paclitaxel can have a number of adverse consequences. Paclitaxel is an irritant and when injected intravenously can cause inflammation of the vein through which it is given. Moreover, if the medication escapes the vein, it can cause tissue damage. In addition, paclitaxel itself has numerous serious side effects that impact over 30% of

all IV paclitaxel patients, including: (i) "neutropenia," a drop in a critical type of white blood cell, putting the patient at greater risk for infection and anemia, (ii) alopecia (*i.e.*, hair loss), (iii) joint and muscle pain, (iv) peripheral neuropathy (*i.e.*, damage to the body's peripheral nervous system) which in paclitaxel patients manifests itself as numbness and tingling of the patients' hands and feet, (v) nausea and diarrhea, (vi) mouth sores, and (vii) "hypersensitivity reaction," which is a catchall term for the fever, facial flushing, chills, shortness of breath, and hives many patients experience immediately after starting an IV paclitaxel infusion. To combat these side effects, patients are often prescribed prophylactic corticosteroids. Further, patients must have access to a medical facility equipped to provide the infusion, including properly trained staff able to correctly administer the precise amount of IV paclitaxel, the timing and amount of which depends on patient height, weight, and cancer diagnosis. Infusions can take as long as three hours to administer. For all of the foregoing reasons, in the decades since paclitaxel's development, multiple companies have attempted to develop methods to deliver it to patients in oral form.

36. However, delivering paclitaxel in oral form also presents complications, including the drug's inability to easily dissolve and be absorbed, particularly given the presence of "P-glycoprotein," a protein found in the cell membrane which aids in discharging foreign, harmful substances from the human body. To overcome resistance from naturally occurring defense mechanisms like "P-glycoprotein," Hanmi, a South Korean pharmaceutical company, developed what it calls "Oral Drug Discovery Platform Technology" – shortened to "Orascovery" – which, if correctly functioning is a "P-glycoprotein inhibitor," preventing that protein from interfering with the body's absorption of paclitaxel. The inhibitor that pairs with paclitaxel is formally known as "HM30181A," and is termed "encequidar."

C. Oraxol's Phase 3 Trial

37. Oraxol's Phase 3 Trial took place outside the United States, entirely in Latin America,[4] from December 2, 2015 to July 25, 2019 and eventually enrolled 402 women diagnosed with metastatic breast cancer.[5] The 402 patients were divided into one of two treatment groups: 265 patients were given Oraxol three times each week; the other 137 patients were given an infusion of IV paclitaxel every three weeks. The primary endpoint of the study was confirmed tumor response rate assessed by a blinded independent radiologic imaging analysis center using the RECIST Criteria, a generally accepted clinical response criteria for efficacy in tumor reduction.

38. Athenex issued several press releases touting the results of the Phase 3 Study while it was ongoing. First, on October 5, 2017, Athenex issued a press release announcing that an independent Drug Safety Monitoring Board ("DSMB") had "unanimously recommended continuation of the study" and had "encouraged the rapid patient recruitment toward the scheduled second interim analysis at 180 patients." The release stated that the DSMB had been "reassured by the expected difference in safety profile between Oraxol and IV paclitaxel," and emphasized that "[i]n particular, the adverse event of painful neuropathy was uncommon with Oraxol treatment." The release also quoted Defendant Kwan as stating that "the unanimous recommendation by the DSMB to continue this study full speed ahead represents an important milestone achieved."

39. Thereafter, on January 16, 2018, Athenex issued a press release announcing that the FDA "ha[d] provided positive feedback on the design of the currently ongoing Phase III

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[4] The Study took place in 45 different medical centers and hospitals in Argentina (15 locations), Guatemala (seven locations), Chile (five locations), Colombia (four locations), the Dominican Republic (three locations), Ecuador (three locations), Peru (three locations), El Salvador (two locations), Honduras (two locations), and Panama (one location).

[5] Metastatic breast cancer is advanced-stage breast cancer that has spread to parts of the body beyond the breast, such as the bones or liver.

Clinical Trial for Oraxol." In this regard, the release specified that the FDA had "indicated that if the study [met] the primary endpoint with an acceptable Benefit/Risk profile, it could be adequate as a single comparative trial to support registration of Oraxol for a metastatic breast cancer indication in the United States." According to the release, "[t]he positive US FDA feedback would allow an Oraxol US registration submission upon successful completion of this single Phase III study." The release also quoted Defendant Lau as stating that "the positive feedback from the FDA on the Phase III Clinical Study Design for Oraxol . . . provides further validation of our regulatory pathway for Oraxol."

40. On February 15, 2018, Athenex announced that the enrollment of patients was on target for the Company to be able to conduct a second interim analysis in the Oraxol Phase 3 clinical trial in the third quarter of 2018. A press release announcing that the planned second interim analysis had been conducted and reviewed by the DSMB was issued on September 5, 2018. According to the release, "[t]he DSMB congratulated Athenex on the rapid patient recruitment and the promising results achieved . . . and recommended that Athenex continue th[e] study and complete the recruitment of patients." The release also quoted Defendant Kwan as stating that "the unanimous recommendation by the DSMB to continue this study represents the achievement of another critical milestone for Oraxol" and that the Company "plan[ned] to provide these confidential unblinded data to regulatory authorities soon to discuss the marketing submission pathways." On January 9, 2019, Athenex announced that target enrollment of 360 patients in the Phase 3 study had been achieved on schedule and reaffirmed that top line data from the study was expected to be available in mid-2019.[6]

[6] Press Release, Athenex, Inc., Athenex Announces Completion of Target Enrollment in the Oraxol Phase III Study (Jan. 9, 2019).

41. On August 7, 2019, Athenex issued a press release with the headline "Athenex Announces Oral Paclitaxel and Encequidar had a Significantly Higher Response Rate Over IV Paclitaxel in a Phase III Pivotal Study in Metastatic Breast Cancer." According to the release, the Phase 3 Trial's "topline data show[ed] that [Oraxol] met the primary efficacy endpoint with statistically significant improvement over IV paclitaxel." Specifically, the release stated that the results showed that 35.8% of the patients administered Oraxol responded to the treatment, compared with 23.4% of the patients administered IV paclitaxel, and that "the proportion of confirmed responders with a duration of response of more than 150 days was 2.5 times higher in the Oral Paclitaxel group than in the IV paclitaxel group." Further, the release announced that "[b]ased on the data cut-off on July 25, 2019, there was a strong trend in progression-free survival . . . and . . . in overall survival . . . favoring Oral Paclitaxel over IV paclitaxel." According to the release, "[a]t the cut-off date, a higher proportion of patients on Oral Paclitaxel compared with IV paclitaxel remained progression-free and Athenex expect[ed] the PFS and OS[7] trend [to] continue to improve upon follow-up." Finally, the release reported that while 57% of the patients administered IV paclitaxel experienced neuropathy, just 17% of the patients administered Oraxol did. The release quoted Defendant Kwan as stating that Athenex would be "preparing [its] NDA submission as soon as possible."

42. In truth, however, as Defendants knew or recklessly disregarded, the Phase 3 Trial was deeply flawed and there was a substantial risk that Oraxol's NDA would be rejected or that the FDA would require additional clinical studies based on these undisclosed flaws, as further described below.

[7] Progression-free survival ("PFS") and overall survival ("OS") are two additional metrics often considered in chemotherapy clinical trials.

1. Athenex's Use of the Abbreviated §505(b)(2) Pathway Created Substantial Undisclosed Risk to Obtaining FDA Approval

43. Athenex sought FDA approval for Oraxol pursuant to the abbreviated approval pathway provided in Section 505(b)(2) of the FDC Act. Section 505(b)(2) is a pathway for new drug products that include changes compared to an existing approved product, such as a new formulation, route of administration, or intended use. The intent behind the §505(b)(2) pathway is to avoid redundant clinical trials. A drug submitted via the §505(b)(2) pathway can be approved based on prior data from studies not conducted by the applicant by relying on previous findings by the FDA of safety and effectiveness of an approved drug. This requires a successful "bridging" of the new drug to the previously approved drug by means of "bioequivalence" studies (a/k/a "bridging studies"), as well as additional studies as needed to fully support efficacy and safety of the new product. Bridging studies are designed to connect the scientific relevance of information developed in a previously approved drug development program to support the product for which an NDA applicant is seeking approval. Once the relevance of such information to the applicant's product is established (*i.e.*, bridged) through such studies, the clinical data from the earlier study can be leveraged by the applicant to streamline its development program and utilize §505(b)(2) for its NDA. As a practical matter, therefore, NDAs submitted under §505(b)(2) are less time and resource intensive since they rely, in part, on existing clinical data. At the same time, however, when FDA-approved treatments already exist, applicants seeking approval for a new drug product face unique and demanding requirements that are difficult to navigate.

44. In the Oraxol NDA, Athenex sought to rely on existing clinical data with respect to IV paclitaxel, which had already been approved by the FDA. However, Oraxol's other ingredient, encequidar, was not an FDA-approved substance.

45. According to CW2, a former Senior Regulatory Staffer at Athenex from mid-2018 until the Fall of 2019, the Defendants' decision to utilize the abbreviated §505(b)(2) pathway to

obtain FDA approval for Oraxol was seriously problematic. Indeed, a study of 226 §505(b)(2) NDAs approved in the five-year period from 2012 to 2016 found that FDA classification types 1 and 2 (new molecular entities and new active ingredients, respectively) were rare because such products would typically be submitted as §505(b)(1) NDAs.[8] CW2 indicated that the Company's failure to obtain prior FDA approval to use the §505(b)(2) pathway created a substantial risk that the Oraxol NDA would be rejected or that the FDA would require additional clinical studies and that these risks were discussed with Athenex's senior leadership.

46. CW2 and outside regulatory consultants Christy Dampousse ("Dampousse") and Bushra Agha ("Agha") advised Athenex's senior leadership, including E. Douglas Kramer ("Kramer"), Athenex's Senior Vice President for Regulatory Affairs and the executive responsible for the Company's regulatory strategy,[9] that Athenex should plan for the likely contingency that the FDA would require another clinical trial be conducted before granting approval for Oraxol. CW2, who worked on the Briefing Book submitted to the FDA in anticipation of the Company's Advisory Committee Meeting with respect to the Oraxol NDA,[10] stated that although early versions had included comments seeking the FDA's guidance with respect to the use of the §505(b)(2) pathway, such comments were removed from the version that was ultimately submitted to the FDA.

47. In addition to the foregoing, CW2 also indicated that Athenex's reliance on the §505(b)(2) pathway was flawed because the Company failed to establish the required

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[8] Ingrid Freije, *et al*., *Review of Drugs Approved via the 505(b)(2) Pathway: Uncovering Drug Development Trends and Regulatory Requirements*, DIA THERAPEUTIC INNOVATION & REGULATORY SCIENCE (Oct. 12, 2018), https://journals.sagepub.com/doi/full/10.1177/2168479018811889.

[9] CW2 met with and/or communicated with Kramer on a daily basis.

[10] The Briefing Book, which CW2 and others worked on, contained detailed information about the proposed drug and Athenex's plan to obtain FDA approval.

comparability between the prior paclitaxel clinical data and the data generated in Oraxol's Phase 3 Trial. CW2 reported that, within the Company, there were many discussions concerning how Athenex could utilize the prior clinical trial data and what additional studies the Company needed to perform in order to adequately submit Oraxol's NDA under §505(b)(2).

48. CW2 explained that these comparability issues between the prior-approved data and the Phase 3 Trial data were openly discussed beginning in 2019 at monthly "Project Team" meetings that CW2 attended along with members of cross-functional teams within Athenex's Oncology Innovation Platform segment, including Kramer, Vice President of Preclinical Operations Michael Smolinski ("Smolinski"),[11] outside regulatory consultants Dampousse and Agha, Senior Director of Quality Inspections Michael Scribner ("Scribner"), Senior Director of Clinical Operations Jane Devane ("Devane"), Director of Clinical Operations John Goldfinch ("Goldfinch") and others. According to CW2, these issues were so grave that they, and their potentially fatal impact on Athenex's effort to obtain FDA approval for Oraxol, were among the primary topics of discussion during Project Team Meetings throughout CW2's tenure at Athenex.

49. Indeed, CW2 reported that by approximately mid-2019 the comparability issues between the prior-approved data and the Phase 3 Trial data were escalated to Athenex's Executive Committee comprised of the Company's U.S.-based senior leadership including Defendant Kwan. Specifically, CW2, along with outside consultants Dampousse and Agha, created a series of PowerPoint presentations outlining the serious risks to obtaining regulatory approval due to these comparability issues, and their assessment that the FDA was unlikely to approve Oraxol based on the Company's existing data. In addition, CW2 indicated that Defendant Lau was aware of these issues and their potential to derail FDA approval through his regular communications with Defendant Kwan and Kramer.

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[11] CW2 reported to Smolinski.

50. CW2 also reported that the comparability issues between the prior-approved data and the Phase 3 Trial data were also raised at a Global Team meeting attended by executives from all three of the Company's segments and members of the Executive Committee that occurred in Buffalo, New York in October 2019.

2. Significant Changes to Chemistry, Manufacturing and Controls Between Earlier Trial Phases and the Phase 3 Trials Created a Significant Undisclosed Risk the Oraxol NDA Would Not Be Approved

51. Chemistry, Manufacturing and Controls ("CMC") are a necessary component of the NDA process. CMC practices ensure that pharmaceutical products are manufactured in such a way as to maintain consistency insofar as their safety and efficacy. They seek to maintain a continuity between the drug used in clinical trials, on the one hand, and the commercial product that will eventually be marketed and made available to the consuming public following FDA approval, on the other. A company's failure to establish sound CMC practices during its Phase 3 clinical trials and through its NDA submission creates a substantial risk that the FDA will not approve the applicant's drug.

52. When changes in CMC practices occur between the earlier stages of drug manufacturing and those associated with the Phase 3 trial and NDA, the FDA commonly requires companies to conduct a series of tests (also referred to as "bridging studies"), to ensure that the adopted changes remain in compliance with regulatory requirements. The results of these studies must be submitted by the applicant to the FDA as part of the NDA process.

53. According to CW2, there were major changes to CMC implemented by Athenex in its Phase 3 Trial that raised numerous "comparability issues." These major changes related to, among other things, (i) selection of different manufacturing sites, specifically, the switch from China to Athenex's Clarence, New York facility, (ii) scale of production, and (iii) changes to manufacturing processes. CW2 raised these issues with Smolinski and informed him that Athenex

would not get FDA approval unless they were resolved. CW2 also raised the comparability issues with respect to CMC with Associate Director of Regulatory Affairs Paola Teegarden and the outside regulatory consultants Dampousse and Agha. CW2 also raised these same concerns with Kramer on multiple occasions. And, according to CW2, the CMC comparability issues were also raised in the Project and Global Team Meetings and featured in the PowerPoint presentations discussed in ¶¶48-50 above.

54. CW3, whose role included reviewing proposed CMC literature that was to be included in Athenex's submissions to the FDA seeking approval for Oraxol, also recalled that Athenex had not conducted sufficient bridging studies given the major changes to CMC practices during Oraxol's Phase 3 clinical trial. According to CW3, "extensive" bridging studies were required given these changes. In CW3's professional opinion, Athenex's failure to provide sufficient information to the FDA in this regard created a substantially high likelihood that the NDA for Oraxol would be rejected or that additional studies would be required by the FDA.

3. That the Phase 3 Trial Was Conducted Entirely in Latin America Created a Significant Undisclosed Risk that the Oraxol NDA Would Not Be Approved

55. Applicants relying entirely on foreign data for NDA approval must satisfy 21 C.F.R. §314.106(b), which states in relevant part that:

> An application based solely on foreign clinical data meeting U.S. criteria for marketing approval may be approved if: (1) ***The foreign data are applicable to the U.S. population and U.S. medical practice***; (2) the studies have been performed by clinical investigators of recognized competence; and (3) the data may be considered valid without the need for an on-site inspection by FDA or, if FDA considers such an inspection to be necessary, FDA is able to validate the data through an on-site inspection or other appropriate means. ***Failure of an application to meet any of these criteria will result in the application not being approvable based on the foreign data alone.***

[Emphasis added.]

56. Here, the Phase 3 Trial was conducted entirely outside of the United States in 10 Latin American countries. According to CW2, the risk that the FDA would recommend that Athenex conduct a new clinical trial of patients representative of the population of the U.S. was something that had been widely discussed at Athenex, including at Project Team Meetings, and that Defendants Kwan and Lau were aware of this issue as well.

4. The Protocols for Assessing ORR Created the Potential for Bias in the Review Process Undermining the Reliability and Certainty of the Data Athenex Presented in the NDA

57. NDA applicants seeking to submit clinical trial data are bound by the strictures of 21 C.F.R. §314.126, which sets a baseline requirement that the study be "adequate and well-controlled." That provision details the numerous prerequisites the applicant must fulfill, including that the study must ensure that "[a]dequate measures are taken to minimize bias on the part of the subjects, observers, and analysts of the data" (21 C.F.R. §314.126(b)(5)) and that "[t]he methods of assessment of subjects' response are well-defined and reliable" (21 C.F.R. §314.126(b)(6)).

58. One common method of reviewing data and eliminating or reducing bias is through the use of a Blinded Independent Central Review ("BICR"), a third party that reviews clinical data and makes assessments. In oncology studies specifically, particularly those in which the primary study endpoint is based on tumor measurement, such as Objective Response Rate ("ORR"), the primary endpoint here, the FDA strongly recommends the use of a BICR.

59. To that end, Athenex retained Intrinsic Imaging LLC ("Intrinsic" or "the BICR"), a Bolton, Massachusetts-based laboratory, as its BICR to assess the ORR in the Phase 3 Trial patients administered either Oraxol or IV paclitaxel.

60. At first glance, the announced results of the Phase 3 Trial appeared to demonstrate a striking success for Oraxol, as reportedly 36% of Oraxol patients purportedly experienced a reduction in tumor size, compared with just 24% of IV paclitaxel patients. This strong ORR result,

along with purportedly favorable PFS and OS trends and what the Company claimed was a strong safety profile, neatly fit with the Company's overall narrative that Oraxol was a clear improvement over IV paclitaxel and that the Phase 3 Trial data was sufficient to support approval of Oraxol's NDA.

61. However, according to CW1, a former Clinical Research Associate at Athenex who worked exclusively on the Phase 3 Trial, many conversations pertaining to trial protocol discrepancies (*e.g.*, the size of tumors and whether a patient qualified to remain in the Phase 3 Trial) occurred between doctors at the trial sites, who were unblinded to the data, and the BICR firm, which was supposed to be "blinded." This had the potential to introduce bias into the supposedly "independent" review process and risked undermining the certainty and reliability of the Trial's ultimate data results.

D. Defendants Begin to Issue a Stream of Materially False and Misleading Statements Concerning the Purported Successes of the Phase 3 Trial

62. The Class Period begins on August 7, 2019, two weeks after the Trial's primary completion date. By this point, all participants in the Phase 3 Trial had been examined and the Company had collected the final data for the Trial's primary outcome measure, the objective response rate.

63. That day, Athenex issued a press release with the headline "Athenex Announces Oral Paclitaxel and Encequidar had a Significantly Higher Response Rate Over IV Paclitaxel in a Phase III Pivotal Study in Metastatic Breast Cancer," announcing that Oraxol had "met the primary efficacy endpoint with statistically significant improvement over IV paclitaxel in a Phase III pivotal study in metastatic breast cancer." According to the release, Oraxol "showed a statistically significant improvement compared to IV paclitaxel on the primary efficacy endpoint, with an ORR of 36% for the Oral Paclitaxel group compared to 24% for IV paclitaxel based on ITT [intent to treat] analysis." In addition, the release stated that "the results showed that the proportion of

confirmed responders with a duration of response of more than 150 days was 2.5 times higher in the Oral Paclitaxel group than in the IV paclitaxel group." Further, the release asserted that "[b]ased on the data cut-off on July 25, 2019, there was a strong trend in progression-free survival . . . and . . . in overall survival favoring Oral Paclitaxel over IV paclitaxel" which Athenex "expect[ed] . . . [would] continue to improve upon follow up." The release also reported that the Oral Paclitaxel group had lower incidence and severity of neuropathy, alopecia, arthralgia and myalgia compared to IV paclitaxel. Finally, the release reported that the incidence of neutropenia was similar in both groups, although there were more incidents of grade 4 neutropenia and infection in the Oraxol group as well as more gastrointestinal side effects.

64. In the same press release, Defendant Kwan, Athenex's CMO, declared Oraxol's Phase 3 Trial a success, adding that "[w]e will be preparing our NDA submission as soon as possible."

65. In the press release, Defendant Lau, Athenex's CEO, was quoted as similarly touting the Trial's results and stating that "***Oral Paclitaxel has the potential to represent a new class of oral anti-cancer drugs***," and "a potential . . . to serve as a cornerstone in chemotherapy in combination with other small molecule anti-cancer drugs, biologics, and immune-oncology treatment approaches, including other drug candidates in [the Company's] oncology pipeline." [Emphasis added.]

66. That same day, August 7, 2019, the Company held its 2Q 2019 earnings call, in which Defendant Lau again praised "the positive top line results" achieved in the Phase 3 trial, stating that:

> [The] Phase III study ***successfully met its primary endpoint, showing a statistically significant and clinically meaningful improvement versus IV paclitaxel.*** We also saw evidence of potential benefits in terms of progression-free survival as well as overall survival.

[Emphasis added.]

67. Oraxol, Defendant Lau continued, was well on its way to an NDA:

> The successful outcome in this trial is a potentially transformative event for Athenex. ***We are currently analyzing the full dataset, but we believe that we are supportive of an NDA filing in metastatic breast cancer. We plan to request a pre-NDA meeting as soon as possible and plan to present the data at a major upcoming scientific meeting.*** . . .
>
> By demonstrating a benefit over conventional IV paclitaxel, ***we now have conclusive evidence from a large randomized study that our technology allows for optimal therapeutic levels of drug exposure via oral delivery***, and the results of this is better outcomes for patients. . . .
>
> This positive result serve[s] as a validation for our Orascovery approach, which we believe will establish a new paradigm in the use of oral anticancer drugs for cancer treatments.

[Emphasis added.]

68. Defendant Kwan explained that Athenex was "working diligently to complete [Oraxol's] NDA submission so that [the Company could] file as soon as possible." Kwan emphasized that "***the FDA previously provided positive feedback to Athenex that they would accept the results of this one pivotal trial for license application in the U.S. if the primary endpoint is met***," and later stated "we already fulfill[ed] our mutual agreement with U.S. FDA that we met our primary endpoint." [Emphasis added.] Lau also stated that the favorable data on progression-free survival ("PFS") and overall survival ("OS") "represent[ed] potential upside" but was "not required:"

> [The FDA] do not even need the PFS and OS. Those are additional. What they request is the ORR, overall response rate, as defined in the protocol to reach statistical significance, and that we use ITT to do the p-value. So we achieved that because it's a single study. So they asked us to use the ITT to use the p-value.
>
> So we achieved already what they have asked for. The PFS and OS is nice additional support that I would think that will make them even more pleased with the data.

69. In response to an analyst's pushback concerning the ORR results from the Phase 3 Trial, Defendant Kwan touted the integrity of the Trial's data and the Company's BICR stating:

> The response rate we saw in this pivotal Phase III study is impressive and is also much higher than the control group.
>
> . . .
>
> Now let me emphasi[ze] the way -- the overall response rate that the FDA would accept is a confirmed overall response rate with 2 consecutive scans. And all these scans were sent to a blinded central lab where they used 2, not 1, 2 individual independent radiologists to assess the scan. And if there is disagreement among the 2 readings, a third independent adjudicator assessed the scan.
>
> ***So this is a very rigorous interpretation of scan on both the IV and the oral arm, and they are completely blinded to treatment assignment.*** And that's the only way the FDA will accept it. So the way -- if you look at the literature, most of the time they will use one scan. If they use 2 scans, they may use an independent reader, but there still will [be] one, not 2, and not adjudicated. So there's a lot of variability if you don't use the FDA regulatory response.
>
> More importantly, the data we are presenting are intent-to-treat. So basically all the patients . . . and it includes patients that drop out because of IV side effects, because of oral side effects. All those are [ac]counted for. So the values you are seeing are extremely pleasing in my eye. And its very well in line with what we see in our Phase II and the other publications in literature, and really testify [sic] the activity of the product.

[Emphasis added.]

70. On that same call, in responding to a question regarding the Company's CMC practices, Defendant Lau claimed "that all the CMC efforts are all in parallel with the clinical studies" and that nothing would "deter our successful launch:"

> ***With regard to your question on CMC, we have been working very diligently to ensure that all our efforts with regard to the successful preparation for the registration of the drug as well as marketing are all in parallel. So I'm delighted to say that all the CMC efforts are all in parallel with the clinical studies to support the success of the program.***
>
> Now I am also delighted to say that, on top of having one plan on the CMC, we have plan B and plan C. ***So therefore, we have been working diligently to ensure that there are no factors that could derail our successful application or submission application for approval, and there will also be no factors that would deter our successful launch based on commercialization effort.*** So the vertical integration has been completed, and in the way we also have fallback plans to ensure that the launch will be a success.

[Emphasis added.]

71. With respect to the Trial's safety data, Defendant Kwan downplayed the poorer neutropenia results for Oraxol versus IV paclitaxel and touted the better neuropathy results for Oraxol as the game changer. In this regard, Defendant Kwan stated that "clinicians on the whole manage the neutropenia and the GI side effect very well using pre-medication" while "[t]hey could not do anything with neuropathy." Defendant Kwan further noted that "[n]europathy is painful. It's chronic. And it's the number one dose limiting issue with paclitaxel."

72. Finally, in response to an analyst's question about commercial preparation, Defendant Lau stated that Athenex was "well advanced with regard to preparing for the success of the Phase III results," had already hired the leader of the marketing team and "evaluated the how-to approach in terms of the marketing effort" and therefore was "confident that [it] [could] launch the drug the day after the approval."

73. The foregoing statements were materially false and misleading because at no point did Defendants disclose existing, known, substantial risks to the NDA's approval including (a) the Company's decision to pursue FDA approval for Oraxol via the abbreviated §505(b)(2) pathway without the FDA's prior authorization; (b) multiple undisclosed CMC changes that had been made during the Phase 3 Trial that disrupted the "comparability" between the prior data submitted in Oraxol's Phase 1 and 2 trials and the Phase 3 Trial for which sufficient bridging studies did not exist; (c) the protocols for assessing ORR created the potential for bias in the review process undermining the reliability and certainty of the data Athenex presented in the NDA; and (d) the possibility that the FDA would recommend that a new clinical trial of patients representative of the population of the U.S. be conducted.

74. Throughout the Class Period, in numerous press releases, public comments, and SEC filings, Defendants made substantially similar statements about Oraxol's Phase 3 Trial and NDA. These additional actionably false and misleading statements include those contained in:

- multiple healthcare conference presentations, including the September 9, 2019 Morgan Stanley Healthcare Conference, and the December 13, 2019 San Antonio Breast Cancer Symposium;

- the Company's press releases and slideshows, including those issued on November 7, 2019, December 13, 2019, February 27, 2020, April 9, 2020, May 7, 2020, August 6, 2020, September 1, 2020, September 8, 2020, November 5, 2020, and December 9, 2020;

- the Company's calls with analysts, including those held on November 7, 2019, February 27, 2020, May 7, 2020, August 6, 2020, September 8, 2020, and November 5, 2020; and

- the Company's September 10, 2020 SPO Offering Documents.

See infra, §VI.

E. The Truth About Oraxol's Phase 3 Trial and NDA Emerges

75. The risk that the Oraxol NDA would not be approved materialized on Monday, March 1, 2021, when, before the market opened, Athenex issued two press releases, one providing 4Q and full year 2020 financial results, and another entitled "Athenex Receives FDA Complete Response Letter for Oral Paclitaxel Plus Encequidar for the Treatment of Metastatic Breast Cancer." In the CRL press release, Athenex explained that the "FDA issues a CRL to indicate that the review cycle for an application is complete and that the application is not ready for approval in its present form." That press release disclosed that the FDA (i) "expressed concerns regarding the ***uncertainty*** over the results of the primary endpoint of objective response rate (ORR) at week 19 conducted by blinded independent centra review (BICR). In this regard, the [FDA] stated that the BICR reconciliation and re-read process may have introduced ***unmeasured bias and influence*** on the BICR"[12] and (ii) "recommended that Athenex conduct a new adequate and well-conducted clinical trial in a patient population with metastatic breast cancer ***representative of the population of the U.S.***" [Emphasis added.]

[12] Athenex clarified in the other press release that the FDA "expressed uncertainty with regard to the ***primary endpoint assessment*** conducted by the blinded independent central review in the Phase III trial," *i.e.*, how the BICR assessed and reviewed data. [Emphasis added.]

76. In addition, the release stated that the that "the FDA indicated its concern of safety risk to patients," including "an increase in neutropenia-related sequalae on the Oral Paclitaxel arm compared with the IV paclitaxel arm" and "determined that additional risk mitigation strategies to improve toxicity, which may involve dose optimization and / or exclusion of patients deemed to be at a higher risk of toxicity, are required to support potential approval of the NDA."

77. On the earnings call held the same day, Defendant Lau claimed that the Company was "surprised and disappointed with the FDA's decision" and that Defendants "believe[d] that Oral Paclitaxel demonstrated a superior efficacy and safety profile in a well-controlled Phase III trial setting." However, he explained, Defendants "remain[ed] committed to exploring all options to unlock value from this asset."

78. Notwithstanding the above, Defendant Lau sounded a hopeful note, claiming:

> The Athenex team is actively working to analyze and respond to the complete response letter. We will request a meeting with the FDA to discuss its concerns as soon as possible. During the meeting, we hope to align with the FDA on the path forward required to obtain approval. The complete response letter represents a disappointing outcome, not only for us, but also for our colleagues, clinicians and patients who helped facilitate development of Oral Paclitaxel in metastatic breast cancer patients.

79. However, on October 11, 2021, Athenex announced that after meeting with the FDA "to review with the FDA a proposed design for a new clinical trial intended to address the deficiencies raised in the [CRL] . . . and discuss the potential regulatory path forward for Oral Paclitaxel in mBC in the U.S.," Athenex had determined not to perform another Phase 3 clinical trial, thereby abandoning its efforts to obtain FDA approval of Oraxol as a treatment for metastatic breast cancer in the U.S.

80. In response to the foregoing disclosures, the Company's common stock plummeted from its Friday, February 26, 2021 closing price of $12.10 per share to a Monday, March 1, 2021

closing price of $5.46, an astounding drop of 55%, corresponding to a drop of $620 million in the Company's market capitalization.

V. ADDITIONAL SCIENTER ALLEGATIONS

81. In addition to the facts pleaded above (including, in particular, those alleged at *supra*, §IV.C. (citing statements of multiple CWs)), the following additional facts support a strong inference of Defendants' scienter.

A. A September 2020 FDA Report Confirms that Defendants, Including Lau and Kwan, Selected the Clinical Research Organization Used in the Phase 3 Trial

82. According to a September 2020 FDA Establishment Inspection Report ("EIR") of Athenex's Buffalo, New York facility, both Lau and Kwan were deeply involved in the Company's selection of one of the clinical research organizations ("CROs") that monitored the Phase 3 Trial and the "country specific regulatory submissions" for each of the Latin American countries in which the Trial took place. CROs are third party organizations contracted to perform specific clinical tasks, including the implementation of a clinical trial, as was the case here. In fact, the EIR notes "that the CEO [Lau] and CMO [Kwan] from Athenex visited [the CRO] prior to their selection as a CRO."

83. That Lau and Kwan were involved in the selection of this CRO comes as no surprise as each of the three CROs Athenex has utilized in its Oraxol clinical trials are related parties, a potential conflict of interest. The CRO utilized in the Phase 3 Trial is CIDAL Limited ("CIDAL"), a Guatemala-headquartered company incorporated in the British Virgin Islands, which Athenex agreed to purchase on June 27, 2019, just before the end of the Trial, in exchange for Athenex common stock, the right to commercialize Oraxol in Australia and New Zealand, and certain undisclosed ***milestone payments***. That Athenex offered CIDAL milestone payments – which are payments dependent on the success or outcome of the Phase 3 Trial – presents a potential conflict of interest.

84. This was not the first time Athenex had employed a related-party CRO to conduct a clinical trial, from which possible conflicts of interest arose. In previous Phase 1 and Phase 2 clinical trials, Athenex employed New Zealand-based Zenith Technology Corporation's subsidiary ZenRx, which is partially owned by Defendant Kwan. Moreover, ZenRx was also offered multiple milestone payments by Athenex.

85. Similarly, Athenex previously employed a Taiwanese company in which Athenex holds approximately 68,000 shares, PharmaEssentia, to help conduct multiple Phase 1 and Phase 2 clinical trials. Additionally, PharmaEssentia also holds the exclusive license to sell Oraxol in Taiwan, Vietnam, and Singapore.

86. In short, each CRO had a pecuniary interest in the success of their respective trials and FDA approval of Oraxol's NDA.

B. Athenex's Elevated Share Price Allowed the Company to Easily Raise $119 Million via Secondary Public Offering

87. At no point in Athenex's history has the Company earned a profit and just seven months after its June 2017 IPO, in January 2018, Defendants were forced to sell more shares to the public through the Company's first SPO to continue to fund operations, including Oraxol's Phase 3 Trial.

88. Toward the end of the Class Period, Athenex ran out of money again. To plug the Company's financing holes, on June 19, 2020, Athenex entered into a senior credit agreement with multiple lenders to borrow up to $225 million, with Oaktree Fund Administration, LLC acting as administrative agent ("Oaktree SCA"). Before the end of the month, the Company borrowed $100 million from the Oaktree SCA, and then drew down another $50 million shortly thereafter.[13] This money did not last either, and with an astonishing level of debt and long-term liabilities (*see* ¶32),

[13] The remaining $75 million of the Oaktree SCA was contingent on the Company progressing with its Oraxol NDA, a sum Athenex never obtained.

Athenex was forced to sell an additional 11.5 million shares at $11.00 per share through a second SPO on September 10, 2020, generating net proceeds of $118.7 million.

89. The SPO was issued pursuant to a prospectus supplement issued that day and a registration statement previously issued on Form S-3 on September 24, 2018 (collectively, the "Offering Documents"). These Offering Documents contained many of the same material misstatements and omissions that Defendants had issued throughout the Class Period, including that Oraxol's "[r]esults demonstrated that the study met its primary endpoint showing statistically significant improvement in overall response rate for Oral Paclitaxel compared to intravenous ("IV") paclitaxel," while omitting that (1) Defendants' choice to utilize the abbreviated §505(b)(2) pathway for seeking FDA approval of Oraxol created a substantial risk the NDA would be rejected or additional clinical studies would be required because Defendants had failed to obtain prior FDA authorization to use this pathway; (2) the NDA's approval was at significant risk due to multiple undisclosed changes that had been made to Oraxol's CMC practices; (3) Athenex had not conducted the Trial free from "biased observation;" and (4) there was a significant risk that the FDA would recommend that a new clinical trial of patients representative of the U.S. population be conducted.

90. In issuing this second SPO in the midst of the Class Period before the truth had been revealed or the undisclosed risks Defendants concealed had materialized, the Company benefited from an elevated share price. Had the market known the truth about Oraxol's Phase 3 Trial and NDA, Athenex's common stock would have traded at a significantly lower price, reducing the amount of money the Company would have raised in the second SPO.

VI. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS

91. Throughout the Class Period, in numerous SEC filings and public statements, Defendants issued materially false and misleading statements about the success of the Company's

Phase 3 Oraxol Trial and the likelihood that the FDA would approve Oraxol's NDA. Defendants' actionably false or misleading Class Period statements are separately enumerated below.

A. August 7, 2019 Press Release and Earnings Call

92. Before the market opened on August 7, 2019, Defendants issued a press release headlined "Athenex Announces Oral Paclitaxel and Encequidar had a Significantly Higher Response Rate Over IV Paclitaxel in a Phase III Pivotal Study in Metastatic Breast Cancer." The press release was attached as an exhibit to the Company's Form 8-K filed with the SEC on August 7, 2019. The body of the press release explained that "topline data" from the Company's Phase 3 Trial demonstrated that:

> [Oraxol] showed a statistically significant improvement compared to IV paclitaxel on the primary efficacy endpoint, with an ORR of 36% for the Oral Paclitaxel group compared to 24% for IV paclitaxel patients based on ITT analysis ($p = 0.01$). Oral Paclitaxel also showed statistically significant improvement compared to IV paclitaxel based on other analyses on populations excluding non-evaluable patients (which would give higher response rates), with p-values ≤ 0.01 in all analyses. In addition, the results showed that the proportion of confirmed responders with a duration of response of more than 150 days was 2.5 times higher in the Oral Paclitaxel group than in the IV paclitaxel group.

93. Defendant Kwan, Athenex's CMO, was quoted in the press release, as stating that:

> This is the second successful Phase III clinical program accomplished by the clinical team this year.[14] We are excited by the positive results in the Phase III pivotal study, demonstrating ***improved ORR for Oral Paclitaxel compared to IV paclitaxel across a full spectrum of analyses*** and lower incidence of neuropathy in the Oral Paclitaxel group. ***We will be preparing our NDA submission as soon as possible.***

[Emphasis added.]

94. Similarly, Defendant Lau, Athenex's CEO and Chairman, added:

> ***Based on the results of the Phase III study***, together with the preliminary results generated in the angiosarcoma study, ***Athenex believes that Oral Paclitaxel has the potential to represent a new class of oral anti-cancer drugs, if approved, based on the findings from this Phase III study showing statistically significant improvement in ORR as monotherapy and longer duration of response over IV***

[14] The other Phase 3 trial did not involve Oraxol or oral paclitaxel.

> ***paclitaxel***, as well as strong trends in improved PFS and OS in patients with metastatic breast cancer.

[Emphasis added.]

95. Likewise, on the earnings call held later that same day, Defendants repeated many of the same misstatements, with Defendant Lau reiterating that:

> ***our Phase III study successfully met its primary endpoint, showing a statistically significant and clinically meaningful improvement versus IV paclitaxel***. We also saw evidence of potential benefits in terms of progression-free survival as well as overall survival.
>
> . . .
>
> The successful outcome in this trial is a potentially transformative event for Athenex. We are currently analyzing the full dataset, but ***we believe that we are supportive of an NDA filing in metastatic breast cancer***. ***We plan to request a pre-NDA meeting as soon as possible and plan to present the data at a major upcoming scientific meeting.***
>
> . . .
>
> By demonstrating a benefit over conventional IV paclitaxel, ***we now have conclusive evidence from a large randomized study that our technology allows for optimal therapeutic levels of drug exposure via oral delivery***, and the results of this is better outcomes for patients.

[Emphasis added.]

96. Similarly, on the same call Defendant Kwan claimed that "oral paclitaxel and encequidar met the primary endpoint, showing ***significant improvement*** over IV paclitaxel in a Phase III pivotal study in metastatic breast cancer" and that "we are now moving ahead toward our first NDA submission from our oral discovery platform," repeating the line a second time that Athenex was "currently working diligently to complete [its] NDA submission so that [it] may file as soon as possible." Kwan also reminded investors that:

> [Athenex] ***announced in January last year the FDA previously provided positive feedback to Athenex that they would accept the results of this one pivotal trial for license application in the U.S. if the primary endpoint is met.***

[Emphasis added.]

97. In touting the integrity of the data, Defendant Kwan praised the Company's BICR, explaining:

> Now let me emphasis the way -- the overall response rate that the FDA would accept is a confirmed overall response rate with 2 consecutive scans. And all these scans were sent to a blind-ed central lab where they used 2, not 1, 2 individual independent radiologists to assess the scan. And if there is disagreement among the 2 readings, a third independent adjudicator assessed the scan.
>
> ***So this is a very rigorous interpretation of scan on both the IV and the oral arm, and they are completely blinded to treatment assignment.*** And that's the only way the FDA will accept it. So the way -- if you look at the literature, most of the time they will use one scan. If they use 2 scans, they may use an independent reader, but there still will one, not 2, and not adjudicated. So there's a lot of variability if you don't use the FDA regulatory response.

[Emphasis added.]

98. Moreover, Kwan was bullish regarding the Oraxol NDA. In response to a question about whether "hitting the primary endpoint of response rate was sufficient for the conditional approval with PFS/OS trend to support full [NDA] approval," Kwan explained:

> Actually, [the FDA] do not even need the PFS and OS. Those are additional. What they request is the ORR, overall response rate, as defined in the protocol to reach statistical significance, and that we use ITT to do the p-value. So we achieved that because it's a single study. So they asked us to use the ITT to use the p-value. ***So we achieved already what they have asked for.*** The PFS and OS is nice additional support that I would think that will make them even more pleased with the data.

[Emphasis added.]

99. Kwan expressed confidence with respect to the objective response rate stating:

> If you look at the 3 endpoints, ***we already achieved the primary endpoint of ORR***, so that's nailed down. But bear in mind ORR is a surrogate endpoint approved by the FDA and recommended for us for breast cancer, and then the next one that they would like is PFS. But the really gold standard for all oncology studies accepted by the FDA is overall survival. So I would say that now that we achieved the primary endpoint of the overall response rate, really the focus should be on the overall survival. And we are very pleasantly surprised that we got such a strong trend even at this early stage.

[Emphasis added.]

100. Additionally, in responding to a question regarding the Company's CMC practices, Defendant Lau claimed "that all the CMC efforts are all in parallel with the clinical studies" and that nothing would "deter our successful launch:"

> ***With regard to your question on CMC, we have been working very diligently to ensure that all our efforts with regard to the successful preparation for the registration of the drug as well as marketing are all in parallel. So I'm delighted to say that all the CMC efforts are all in parallel with the clinical studies to support the success of the program.***
>
> Now I am also delighted to say that, on top of having one plan on the CMC, we have plan B and plan C. ***So therefore, we have been working diligently to ensure that there are no factors that could derail our successful application or submission application for approval, and there will also be no factors that would deter our successful launch based on commercialization effort.*** So the vertical integration has been completed, and in the way we also have fallback plans to ensure that the launch will be a success.

[Emphasis added.]

101. The foregoing statements in ¶¶92-100 were materially false and misleading because, at the time they were made Defendants knew, or recklessly disregarded, but failed to disclose that:

(a) the Company's decision to pursue FDA approval for Oraxol via the abbreviated §505(b)(2) pathway without the FDA's prior authorization created a significant risk that the NDA would be rejected or that additional clinical studies would be required;

(b) Oraxol's NDA was at significant risk due to multiple undisclosed CMC changes that had been made during the Phase 3 Trial that disrupted the "comparability" between the prior data submitted in Oraxol's Phase 1 and 2 trials and the Phase 3 Trial;

(c) the protocols for the evaluation of Trial data injected the potential for bias into the BICR process and risked undermining the certainty and reliability of the data Athenex presented; and

(d) there was a significant risk that the FDA would recommend that a new clinical trial of patients representative of the U.S. population be conducted.

B. September 9, 2019 Presentation at the Morgan Stanley Healthcare Conference

102. On September 9, 2019, at the Morgan Stanley Healthcare Conference, Defendant Lau, the Company's CEO, presented on Oraxol's Phase 3 Trial and upcoming NDA submission, which he stated would be ready for NDA submission "within the next 6 months." According to Lau, the fact that Oraxol had met the Trial's primary endpoint – ORR – was the key to the NDA submission because the "FDA already indicated . . . in an agreement in the minutes that they will -- they consider that the ORR data was -- will be sufficient for them to approve the drug." According to Lau, Athenex had "an agreement with U.S. FDA that the ORR result would be sufficient for them to approve."

103. With respect to the timing of the NDA, Defendant Lau stated that:

> We are planning to submit our NDA in the first quarter of next year. We also indicated that we are crossing a pre-NDA meeting very soon. I mean very soon. And I can share with you that the dossier is already ready to be submitted to NDA. I'm just very cautious. I want the dossier to be perfect with regards to ask the right questions with FDA and get a consensus with regard to the scope of the NDA before we file the NDA to the FDA for consideration, for approval.

104. According to Lau there were no CMC issues:

> ***We have solved all the CMC issue. We are ready.*** There are two logistic issues that we have to handle. The first logistic issue is that we need to have very pure paclitaxel to start with because paclitaxel, not all of them are the same. We need to have pure paclitaxel that the specification in a capsule, after around one-and-a-half, two years, there still -- sort of with these specifications, that it still can be in the market, in something like a dry powder in a vial that is fuel for (inaudible). It's much easier to handle.

[Emphasis added.]

105. The foregoing statements in ¶¶102-104 were materially false and misleading because, at the time they were made Defendants knew, or recklessly disregarded, but failed to disclose that:

(a) the Company's decision to pursue FDA approval for Oraxol via the abbreviated §505(b)(2) pathway without the FDA's prior authorization created a significant risk that the NDA would be rejected or that additional clinical studies would be required;

(b) Oraxol's NDA was at significant risk due to multiple undisclosed CMC changes that had been made during the Phase 3 Trial that disrupted the "comparability" between the prior data submitted in Oraxol's Phase 1 and 2 trials and the Phase 3 Trial;

(c) the protocols for the evaluation of Trial data injected the potential for bias into the BICR process and risked undermining the certainty and reliability of the data Athenex presented; and

(d) there was a significant risk that the FDA would recommend that a new clinical trial of patients representative of the U.S. population be conducted.

C. November 7, 2019 Press Release and Earnings Call

106. On November 7, 2019, Athenex issued a press release announcing third quarter 2019 financial results and providing a corporate update. The press release was attached as an exhibit to the Company's Form 8-K filed with the SEC on November 7, 2019. In this release, the Company stated that the anticipated Oraxol NDA was "on track" and that the Company "[e]xpect[ed] to submit an NDA for Oral Paclitaxel in metastatic breast cancer (Q1 2020)."

107. On the earnings call held that day, Defendant Lau explained that the Company "ha[s] several major catalysts upcoming, including an oral presentation of oral paclitaxel and

encequidar data at the upcoming San Antonio Breast Cancer Meeting and two anticipated NDA filings in early 2020 [including Oraxol], which [the Company] expect[ed] to follow with regulatory filings in additional global markets."

108. According to Defendant Lau, Athenex had big plans for Oraxol:

> ***Oral paclitaxel will become our flagship product to build our global brand upon approval.*** Currently, we are preparing to discuss the Phase III data with the FDA who previously indicated that this study, if successful, could be adequate as a single comparative trial to support registration of oral paclitaxel and encequidar in the U.S. for metastatic breast cancer. ***The positive data we reported in August was a major milestone for Athenex, adding to the strong body of clinical evidence that our oral discovery platform is working as designed.*** This significantly de-risks the clinical programs that follow, including oral docetaxel, oral oratecan, oral topotecan and oral eribulin. ***Based on the successful outcome of the Phase III study, oral paclitaxel has demonstrated a very strong clinical profile from both efficacy and safety perspectives.***
>
> ***This study met its primary endpoint showing statistically significant improvement in overall response rate compared to IV paclitaxel.*** There were also strong trends in progression-free survival and overall survival of oral paclitaxel, as well as a greater proportion of confirmed responders on oral paclitaxel with duration of response greater than 150 days versus IV paclitaxel. Neuropathy was much less frequent with oral paclitaxel, which we believe is an important differentiating factor. Importantly, this clinical outcome highlights the potential of our oral chemotherapy pipelines, which we expect to develop for a range of cancers and combination approaches as part of product life cycle management.

[Emphasis added.]

109. During his prepared remarks, Defendant Kwan indicated that Athenex expected to file its NDA submission for Oraxol in the first quarter of 2020:

> ***We are moving ahead confidently towards our first NDA submission for our oral discovery platform based on the strong data we previously reported for our lead candidate, oral paclitaxel and encequidar . . . We were very excited to announce that the study met its primary endpoint, showing statistically significant improvement over IV paclitaxel in confirmed overall tumor response rate based on ITT analysis, oral paclitaxel showed an overall response rate of 36% compared to 24% for IV paclitaxel patients . . . Collectively, the results of this pivotal study represent an important milestone in the development of this new class of oral anti-cancer drugs.*** Based on the Phase III results, we see compelling evidence in terms of the efficacy and safety of oral paclitaxel's clinical benefit for patients with metastatic breast cancer. We believe it will be competitive and has the potential to become a cornerstone in the treatment of metastatic breast cancer.

[Emphasis added.]

110. When pressed on the Company's interactions with the FDA, Defendant Kwan reiterated that:

> ***[W]e are actively engaging the FDA in communications, in discussion regarding the Oraxol submission and we are on track to file first quarter. . . To put it again on the record our previous dialog with the FDA consultation is based on the primary endpoint of response rate.*** The PFS and OS are secondary endpoints and they do not – they are not a requirement for the FDA consideration.

[Emphasis added.]

111. Additionally, regarding the Company's CMC practices, Defendant Kwan stated that:

> ***[W]e are actively preparing for the submission of the CMC sections.*** As indicated to you that we are contemplating that to be a very important product with a substantial market potential. So on top of resolving all the logistics in the API and then the product manufacturing, we are also looking into Plan B and Plan C vis-à-vis, we have both the primary supplier that is ourselves. We also have picked up alternative suppliers to ensure that when we are able to launch a product, there will be no interruptions. ***All these activities are yet to be ongoing and Mr. Jeff Yordon and myself are actively engaging to ensure that all this are smooth – process are smooth and there will be no interruptions to our success.***

[Emphasis added.]

112. In his prepared remarks, COO Jeffrey Yordon discussed the Company's expansion of its commercial infrastructure in anticipation of the commercial launch of Oraxol. According to Yordon, Athenex was "prepared to capture significant market share as efficiently as possible, establishing [Oraxol] as the chemotherapy of choice for metastatic breast cancer."

113. The foregoing statements in ¶¶106-112 were materially false and misleading because, at the time they were made Defendants knew, or recklessly disregarded, but failed to disclose that:

(a) The Company's decision to pursue FDA approval for Oraxol via the abbreviated §505(b)(2) pathway without the FDA's prior authorization created a significant risk that the NDA would be rejected or that additional clinical studies would be required;

(b) Oraxol's NDA was at significant risk due to multiple undisclosed CMC changes that had been made during the Phase 3 Trial that disrupted the "comparability" between the prior data submitted in Oraxol's Phase 1 and 2 trials and the Phase 3 Trial;

(c) the protocols for the evaluation of Trial data injected the potential for bias into the BICR process and risked undermining the certainty and reliability of the data Athenex presented; and

(d) there was a significant risk that the FDA would recommend that a new clinical trial of patients representative of the U.S. population be conducted.

D. December 13, 2019 Press Release and San Antonio Breast Cancer Symposium Presentation

114. On December 13, 2019, Defendants issued a press release and presentation attached to the Company's SEC Form 8-K announcing that the Company would present that day at the San Antonio Breast Cancer Symposium. The release and presentation were attached as exhibits to the Company's Form 8-K filed on December 13, 2019.

115. The press release, titled "Athenex Announces Superior Response and Survival with Lower Neuropathy of a Novel Oral Paclitaxel versus IV Paclitaxel in Treatment of Metastatic Breast Cancer," announced results of the Phase 3 Trial and quoted Defendant Kwan as stating that:

> Oral paclitaxel and encequidar is the first oral taxane to demonstrate in a Phase III study statistically significant improvement in response rate and median overall survival compared to IV paclitaxel, in the treatment of metastatic breast cancer while associated with a much lower incidence and severity of neuropathy. We believe these data suggest the potential for oral paclitaxel and encequidar to provide an important advance in the management of patients with metastatic breast cancer.

116. The presentation repeated multiple of the prior misstatements, including that the Trial had been conducted pursuant to a "[b]linded and adjudicated central independent review," that "[o]ral paclitaxel and encequidar is the first oral taxane in a Phase III trial to demonstrate a

significant improvement in confirmed overall response rate compared to IV paclitaxel," and concluding that "Oral paclitaxel and encequidar provides an important oral therapeutic option for patients with metastatic breast cancer, representing a meaningful improvement in the clinical profile of paclitaxel."

117. The foregoing statements in ¶¶114-116 were materially false and misleading because, at the time they were made Defendants knew, or recklessly disregarded, but failed to disclose that:

(a) The Company's decision to pursue FDA approval for Oraxol via the abbreviated §505(b)(2) pathway without the FDA's prior authorization created a significant risk that the NDA would be rejected or that additional clinical studies would be required;

(b) Oraxol's NDA was at significant risk due to multiple undisclosed CMC changes that had been made during the Phase 3 Trial that disrupted the "comparability" between the prior data submitted in Oraxol's Phase 1 and 2 trials and the Phase 3 Trial;

(c) the protocols for the evaluation of Trial data injected the potential for bias into the BICR process and risked undermining the certainty and reliability of the data Athenex presented; and

(d) there was a significant risk that the FDA would recommend that a new clinical trial of patients representative of the U.S. population be conducted.

E. February 27, 2020 Press Release and Earnings Call

118. On February 27, 2020, Athenex issued a press release on Form 8-K filed with the SEC announcing fourth quarter and full year 2019 financial results and providing a corporate update. The press release was attached as an exhibit to the Company's Form 8-K filed with the

SEC on February 27, 2020. In this release, the Company stated the "Oral Paclitaxel NDA submission is on track" and that the "[f]inal FDA meeting has been scheduled for early April and the Company plans to submit an NDA in the US shortly thereafter."

119. In the earnings call held that day, Defendant Lau stated that:

> ***The planned NDA submission for oral paclitaxel is supported by a strong clinical data package including the results of our Phase III trial in metastatic breast cancer completed in 2019. This trial successfully met its primary efficacy end point showing a statistically significant improvement on overall response rate for oral paclitaxel compared to IV Paclitaxel.*** We'll provide an update on the trial at the San Antonio Breast Cancer Symposium in December, also announcing in the conference that oral paclitaxel demonstrated a significant improvement in overall survival.
>
> I would note that this is the first Oral Taxane to demonstrate a significant improvement in response rate and overall survival in a Phase III study with much less Neuropathy. ***We are on track to submit a NDA in the U.S. for oral paclitaxel.*** We will not be providing additional details at this time, but we'll share news of NDA acceptance by the U.S. FDA once it is confirmed.

[Emphasis added.]

120. In his prepared remarks, Defendant Kwan praised the Trial and provided a recap of the data the Company had presented at the San Antonio Breast Cancer Symposium stating:

> We had announced earlier in 2019 that our Phase III study in metastatic breast cancer successfully met its primary end point. ***In the final analysis of the primary end point, we showed that patients treated with oral paclitaxel had an overall response rate of 40.4% compared with 25.6% for patients treated with IV paclitaxel, a difference of 14.8%. This was statistically significant with a p-value of 0.005.*** These results were based on prespecified, modified intent-to-treat analysis.
>
> We were very excited to announce at San Antonio that treatment with oral paclitaxel also results in an improvement in overall survival in that trial. In the prespecified mITT population, the median overall survival for patients treated with oral paclitaxel was 27.9 months compared to 16.9 months for those on IV paclitaxel, a difference of 11 months. . . .
>
> Overall survival was the secondary endpoint of the trial. . . .
>
> We believe the safety data of oral paclitaxel will be extremely compelling for both doctors and patients. There was an impressive reduction in neuropathy. . . .

> Furthermore, GI adverse events were manageable with probiotics therapy. Given the strong efficacy data and excellent tolerability of oral paclitaxel, together with the convenience of an oral route of administration, we are extremely confident about our unique and competitive product profile. We believe that the body of data we have generated will help establish oral paclitaxel as the treatment of choice for patients receiving chemotherapy for metastatic breast cancer.

[Emphasis added.]

121. In response to an analyst's question concerning the timing of the NDA filing, Defendant Kwan stated that Athenex was "very confident with the data package [it] already [had] from the Phase III study and from [its] ongoing discussion with the FDA," and that its scheduled "discussion with the FDA in early April would be the last piece we want to cross off before we make the submission." Later, in response to another analyst's inquiries on the same topic, Defendant Kwan stated:

> [W]e have a very strong package from our Phase III program in accordance with the FDA designed confirmed overall response rate as an approvable end point for Abraxane. ***So our clinical study clearly demonstrates that based on the primary endpoint, we win very convincingly over well-performing active control arm with a significant – very significant p-value both in the protocol-specified analysis and the ITT.*** And in addition, all the survival analysis were in the right direction, especially the overall survival trend in the protocol-specified mITT even at early stage is statistically significant with a difference of 11 months in favor of the Oraxol. So we are confident with the efficacy side.
>
> The safety side, the fact that we were able to achieve a dramatic reduction in the clinically relevant neuropathy is a strong point . . . So we are very confident with regarding the clinical data set as it stands to fulfill whatever the FDA would need for approval.

[Emphasis added.]

122. Additionally, Defendant Kwan, in responding to a question about Athenex's upcoming FDA meeting regarding the Oraxol NDA, preemptively added some "flavor" regarding Oraxol's CMC practices:

> I will also give a little bit more flavor why we call this as the final FDA meeting. I think this is behind your question. ***We already have ongoing dialogue, and they have been checking off all the preclinical CMC questions one-by-one with the FDA. And we – as I indicated, we believe our clinical package is really strong enough.*** So really, the final discussion is really on the normal formality of the

> submission format, checking up those last items. But more importantly, as I indicate, we wanted the opportunity to optimize our labeling discussion.

[Emphasis added.]

123. Defendant Lau then followed up with a discussion of Oraxol's CMC practices as well:

> Just to add one more comment is that, as Rudolf [Kwan] has already indicated, the discussion or communication of FDA is ongoing ***and I'm delighted to say that [SC], FDA has indicated that all the discussion with regard to the preclinical as well as the CMC package everything, the discussion was very satisfactory.*** So therefore, the last – this is the reason why Dr. Kwan is saying that this will be the last piece of information more on the discussion with regard to today's clinical data.

[Emphasis added.]

124. Finally, Defendant Lau closed with the assurance that the Oraxol NDA "will come very soon, pending on our discussion with the FDA, which I have full confidence that this is going to come very soon."

125. The foregoing statements in ¶¶118-124 were materially false and misleading because, at the time they were made Defendants knew, or recklessly disregarded, but failed to disclose that:

(a) The Company's decision to pursue FDA approval for Oraxol via the abbreviated §505(b)(2) pathway without the FDA's prior authorization created a significant risk that the NDA would be rejected or that additional clinical studies would be required;

(b) Oraxol's NDA was at significant risk due to multiple undisclosed CMC changes that had been made during the Phase 3 Trial that disrupted the "comparability" between the prior data submitted in Oraxol's Phase 1 and 2 trials and the Phase 3 Trial;

(c) the protocols for the evaluation of Trial data injected the potential for bias into the BICR process and risked undermining the certainty and reliability of the data Athenex presented; and

(d) there was a significant risk that the FDA would recommend that a new clinical trial of patients representative of the U.S. population be conducted.

F. April 9 and May 7, 2020 Press Releases and May 7, 2020 Earnings Call

126. On April 9, 2020, Athenex issued a press release announcing that:

> [Athenex had] recently participated in a constructive meeting with the U.S. Food and Drug Administration (FDA) as scheduled, to discuss the clinical section of the New Drug Application (NDA) for oral paclitaxel and encequidar for the treatment of metastatic breast cancer. ***The Company is on track to submit the NDA in accordance with the FDA's guidance, and will provide a further update when the FDA's official response to the filing becomes available.***

[Emphasis added.]

127. Thereafter, on May 7, 2020, Defendants issued a press release announcing 1Q 2020 financial results. The press release was attached as an exhibit to the Company's Form 8-K filed with the SEC on May 7, 2020. The press release reiterated that "[t]he Company [had] participated in a constructive meeting with the FDA, as scheduled, to discuss the clinical section of the NDA for Oral Paclitaxel for the treatment of metastatic breast cancer, and is on track to submit the NDA."

128. The press release also quoted Defendant Lau as stating that (i) "the NDA for Oral Paclitaxel is on track to be submitted soon," (ii) Oraxol had a "strong clinical data package[], a reflection of the very capable execution by our R&D and clinical teams," and (iii) Defendants were "continuing with . . . pre-commercial activities for Oral Paclitaxel, many of which can be completed virtually, to ensure [the Company was] well positioned for commercial launch."

129. The press release also cited "FDA acceptance of the NDA for Oral Paclitaxel for metastatic breast cancer" as among the Company's "upcoming milestones."

130. On the earnings call held the same day, Defendants continued to make positive statements concerning the anticipated success of Oraxol's upcoming NDA and its eventual commercialization.

131. Defendant Kwan stated that the "NDA submission for oral paclitaxel [was] imminent," explaining that Athenex had met with the FDA in early April to discuss the "clinical package" for the NDA. Kwan characterized this meeting as "one of the final steps" before submission. According to Kwan, at the April meeting, the FDA had provided the Company "with guidance on further assessment of survival endpoints."

132. During the call, Defendant Cook stated that Athenex was "busy finalizing preparations for a successful launch of oral paclitaxel" and that based on the "strength" of the clinical data that had been presented at the San Antonio conference, Athenex was "well positioned to achieve [its] strategic goal of becoming the preferred chemotherapy in metastatic breast cancer," which Cook touted as "an important first step in establishing [the Company's] leadership in oncology." Cook also touted the market share that Oraxol would address upon approval, stating:

> Oral paclitaxel is an exciting drug that has the potential to be practice changing. We have shown in our Phase III study a superior response rate and also survival benefit as well as lower neuropathy. Our team is excited about the clinical results, and are further driven by the encouraging feedback from most of the U.S. clinical experts that we spoke to, who have reviewed the clinical data.
>
> The market opportunity is compelling. Our market research shows that oral paclitaxel will be prescribed mostly for breast cancer patients who are hormone positive, HER2-negative or who are triple negative. This represents approximately 70,000 patients annually in the U.S.
>
> We also know that in metastatic breast cancer, chemotherapy is used mostly after CDK4/6s and endocrine therapy, and single-agent chemotherapy is preferred. So we are very enthusiastic about commercial prospects.

133. Cook also stated that the "company remain[ed] on track with previously planned prelaunch activities" and was "rounding out [its] medical science liaison team and [had] recently hired [a] team leader." In addition, Cook stated that Athenex "still plan[ned] to onboard [its] oral

paclitaxel sales team in the second half of the year" which would then be "supplement[ed] . . . with another 25 hires approximately 3 to 6 months post launch." Further, Cook stated that Athenex had "converged on [its] specialty pharmacy distribution model and selected [its] specialty pharmacy providers." COO of Athenex Pharmaceuticals Defendant Jeffrey Yordon stated that the Company was "building inventory that [would] allow [Athenex] to have an adequate amount of commercial supply at the time of launch and [was] continuing to enhance [its] manufacturing processes."

134. In response to an analyst's question seeking more "color" on what the FDA was looking for in terms of overall survival data, Defendant Kwan emphasized that the Trial's ORR result was the pivotal metric but that the data on overall survival also had been positive, stating:

> As we all know, the study, the pivotal study for oral paclitaxel was designed for superiority over IV paclitaxel based on overall response rate. So we were extremely happy that the results came up very positively.
>
> Along with it, we look at the consistency in survival, and we were very, very happy that the outcome even at an ongoing analysis show consistency in the survival with the overall response rate, especially in the overall survival. So this overall survival from the ongoing analysis obviously was discussed with the FDA, and they basically inform us that, certainly, survival will be part of the risk-benefit assessment. And they gave us guidance how to continue with this ongoing analysis of the survival, especially the overall survival.

135. Additionally, Defendant Kwan pushed back at the suggestion that the FDA's provision of guidance with respect to overall survival data meant that additional data needed to be gathered for the NDA, stating that Athenex "believe[d] [it] ha[d] complete information to go in with a full submission."

136. The foregoing statements in ¶¶126-135 were materially false and misleading because, at the time they were made Defendants knew, or recklessly disregarded, but failed to disclose that:

(a) The Company's decision to pursue FDA approval for Oraxol via the abbreviated §505(b)(2) pathway without the FDA's prior authorization

created a significant risk that the NDA would be rejected or that additional clinical studies would be required;

(b) Oraxol's NDA was at significant risk due to multiple undisclosed CMC changes that had been made during the Phase 3 Trial that disrupted the "comparability" between the prior data submitted in Oraxol's Phase 1 and 2 trials and the Phase 3 Trial;

(c) the protocols for the evaluation of Trial data injected the potential for bias into the BICR process and risked undermining the certainty and reliability of the data Athenex presented; and

(d) there was a significant risk that the FDA would recommend that a new clinical trial of patients representative of the U.S. population be conducted.

G. August 6, 2020 Press Release and Earnings Call

137. On August 6, 2020, Athenex issued a press release reporting its financial results for the year ended June 30, 2020, and describing the status of regulatory activities with respect to Oraxol. The press release was attached as an exhibit to the Company's Form 8-K filed with the SEC on August 6, 2020. The headlines of the release reported that "[r]egulatory progress for Oral Paclitaxel . . . [was] on track," and that there had been "continued momentum in building commercialization infrastructure and supply chain for Oral Paclitaxel." The release also quoted Defendant Lau as stating that Athenex was "completing [its] commercialization infrastructure and [its] supply chain, further positioning Athenex as a commercial-stage biopharmaceutical company." The release also reported that Athenex had "strengthened [its] balance sheet" by entering into a $225 million loan agreement with Oaktree Capital Management, L.P. and a $50 million revenue interest financing agreement with Sagard Healthcare Royalty Partners, L.P. According to Defendant Lau, these financing agreements provided Athenex "with the financial

flexibility to continue advancing the development and commercialization of [the Company's] lead drug candidates."

138. On the earnings call with analysts held the same day, Defendant Lau stated that Athenex's "commercial team [was] putting all the key elements in place for successful oral paclitaxel launch," and declared that the Company's "goal" was "to make oral paclitaxel be chemotherapy of choice for metastatic breast cancer."

139. In his prepared remarks, Defendant Cook emphasized that preparations for the expected commercial launch of Oraxol were "at an advanced stage," stating:

> It is our #1 priority to ensure that our team is prepared to enter the field as soon as we have FDA approval.
>
> . . .
>
> Oral paclitaxel is an exciting launch that has the potential to be practice changing. We have shown in our Phase III study, a superior response rate and also survivor benefits as well as lower neuropathy. Our team is excited by the clinical results and are further driven by the encouraging feedback from mostly U.S. clinical experts that we felt to have used the clinical data.
>
> The market opportunity is compelling. Our market research shows that oral paclitaxel will be prescribed mostly for breast cancer patients who are hormone positive, or too negative or who are triple negative. This represents approximately 70,000 patients annually with U.S. We also know that in metastatic breast cancer, chemotherapy is used mostly after CDK4/6 and endocrine therapy. And single-agent chemotherapy is preferred. So we are very enthusiastic about the commercial prospects.

140. In addition, Defendant Cook also stated that market awareness of Oraxol was "high" and emphasized that clinical experts were "impressed with [Oraxol's] overall efficacy profile, the response rates[,] . . . the overall survival[, and] the significant decrease in neuropathy," while they viewed Oraxol's "toxicity profiles [as] being manageable."

141. When asked whether he expects any "surprises" from the FDA regarding the Oraxol NDA, Defendant Kwan struck a bullish tone, stating:

> [W]hen I follow what the FDA has been announcing recently, what they are approving recently, that the FDA oncology director, Dr. Pazdur, has publicly announced that the FDA is focusing on oral anti-cancer treatment, and they will be – because they have a major role to play in the COVID-19 to keeping patients safe at home and also keeping the health service provider lower burden.
>
> So those are very encouraging public announcements from the FDA. ***So I would anticipate, if any surprises, those will be the upside surprises we'll be looking for.***

[Emphasis added.]

142. The foregoing statements in ¶¶137-141 were materially false and misleading because, at the time they were made Defendants knew, or recklessly disregarded, but failed to disclose that:

(a) The Company's decision to pursue FDA approval for Oraxol via the abbreviated §505(b)(2) pathway without the FDA's prior authorization created a significant risk that the NDA would be rejected or that additional clinical studies would be required;

(b) Oraxol's NDA was at significant risk due to multiple undisclosed CMC changes that had been made during the Phase 3 Trial that disrupted the "comparability" between the prior data submitted in Oraxol's Phase 1 and 2 trials and the Phase 3 Trial;

(c) the protocols for the evaluation of Trial data injected the potential for bias into the BICR process and risked undermining the certainty and reliability of the data Athenex presented; and

(d) there was a significant risk that the FDA would recommend that a new clinical trial of patients representative of the U.S. population be conducted.

H. September 1, 2020 Press Release

143. On September 1, 2020, Athenex issued a press release announcing the FDA's "Acceptance for Filing of [the Company's] U.S. NDA for Oral Paclitaxel and Encequidar in

Metastatic Breast Cancer with Priority Review," adding that "the FDA ha[d] set a target action date of February 28, 2021," and had "communicated that it [was] not currently planning to hold an advisory committee meeting to discuss the application."

144. The press release explained that:

> The Oral Paclitaxel NDA submission is supported by data from a single pivotal Phase III study of Oral Paclitaxel for the treatment of metastatic breast cancer. The study is a randomized, controlled clinical trial designed to compare the safety and efficacy of Oral Paclitaxel monotherapy versus IV paclitaxel monotherapy. As previously reported, the study achieved its primary endpoint showing statistically significant improvement in overall response rate, along with a lower neuropathy, for Oral Paclitaxel compared to IV Paclitaxel.

145. The press release also quoted Defendant Kwan as stating that "[w]e are working diligently with the FDA on this Priority Review to bring Oral Paclitaxel to patients with metastatic breast cancer as quickly as possible. … Intravenous (IV) Paclitaxel is a foundational chemotherapy in multiple tumor types and we plan to invest in broadening the label and uses for Oral Paclitaxel."

146. The foregoing statements in ¶¶143-145 were materially false and misleading because, at the time they were made Defendants knew, or recklessly disregarded, but failed to disclose that:

(a) The Company's decision to pursue FDA approval for Oraxol via the abbreviated §505(b)(2) pathway without the FDA's prior authorization created a significant risk that the NDA would be rejected or that additional clinical studies would be required;

(b) Oraxol's NDA was at significant risk due to multiple undisclosed CMC changes that had been made during the Phase 3 Trial that disrupted the "comparability" between the prior data submitted in Oraxol's Phase 1 and 2 trials and the Phase 3 Trial;

(c) the protocols for the evaluation of Trial data injected the potential for bias into the BICR process and risked undermining the certainty and reliability of the data Athenex presented; and

(d) there was a significant risk that the FDA would recommend that a new clinical trial of patients representative of the U.S. population be conducted.

I. November 5, 2020 Press Release and Earnings Call

147. On November 5, 2020, Athenex issued a press release announcing third quarter 2020 financial results and providing a corporate update, stating that "[t]he U.S. Food and Drug Administration (FDA) accepted an NDA for Oral Paclitaxel for the treatment of metastatic breast cancer and has granted the application Priority Review. Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target action date of February 28, 2021." The press release was attached as an exhibit to the Company's Form 8-K filed with the SEC on November 5, 2020.

148. The press release quotes Defendant Lau as stating that "Oral Paclitaxel has a compelling efficacy, and tolerability profile that we believe positions it to potentially become the chemotherapy of choice in metastatic breast cancer. Our supply chain is in place and we are finalizing our commercial plans, with the goal of launching in the U.S. upon approval in the first quarter of 2021."

149. On the earnings call that day, Defendant Lau noted that "[t]he FDA appears supportive of therapies that can help keep patients on therapy in the current pandemic environment" and that Athenex's "commercial team [was] now completely focused on putting all the key elements in place for a successful Oral Paclitaxel launch." Lau also touted Oraxol's "market opportunity" stating:

> The market opportunity in metastatic breast cancer is significant. Market research shows that Oral Paclitaxel will initially be prescribed mostly for breast cancer patients who are hormone-positive, HER2 negative or who are triple negative. These settings represent roughly 70,000 patients annually in the U.S. Certain

> pathways exist to expand the total addressable market. These expansion opportunities include additional combination trials, other settings where Oral Paclitaxel represent standard of care and additional cancer indications.

150. In his prepared remarks, Defendant Kwan noted that the "[o]ngoing dialogue with the FDA [was] encouraging" and that Defendants were "pleased with our progress to date." Defendant Kwan also noted that Athenex had "4 Oral Paclitaxel abstracts accepted for poster presentation at the San Antonio Breast Cancer Virtual Symposium taking place December 8 to 11" including posters on "a PFS [progression-free survival] and OS [overall survival] update from [Athenex's] pivotal Phase III trial in metastatic breast cancer . . . neuropathy and . . . the management of GI side effects."

151. Defendant Cook added that "[t]he final stages of commercial planning for Oral Paclitaxel [were] underway" and that "[t]he company [was] prepared to launch immediately upon the FDA action date of February 28, 2021 or earlier."

152. Finally, according to Defendant Kwan, the Company had been in constant contact with the FDA: "we have been very busy focusing on two submissions. So the whole team, when you got two MPA reveal with the FDA and especially with the [whole] show being a parity review, the interaction with the FDA is really very constant and interactive and really focusing on knitting down those 2 approvals from our perspective."

153. The foregoing statements in ¶¶147-152 were materially false and misleading because, at the time they were made Defendants knew, or recklessly disregarded, but failed to disclose that:

(a) The Company's decision to pursue FDA approval for Oraxol via the abbreviated §505(b)(2) pathway without the FDA's prior authorization created a significant risk that the NDA would be rejected or that additional clinical studies would be required;

(b) Oraxol's NDA was at significant risk due to multiple undisclosed CMC changes that had been made during the Phase 3 Trial that disrupted the "comparability" between the prior data submitted in Oraxol's Phase 1 and 2 trials and the Phase 3 Trial;

(c) the protocols for the evaluation of Trial data injected the potential for bias into the BICR process and risked undermining the certainty and reliability of the data Athenex presented; and

(d) there was a significant risk that the FDA would recommend that a new clinical trial of patients representative of the U.S. population be conducted.

J. December 9, 2020 Press Release

154. On December 9, 2020, Athenex issued a press release headlined "Athenex Presents Updated Phase 3 Data on Survival and Tolerability Associated with Oral Paclitaxel and Encequidar in Patients with Metastatic Breast Cancer." The Company announced that data that would be presented at the 2020 San Antonio Breast Cancer Symposium "indicates benefits of oral paclitaxel and encequidar (oral paclitaxel) versus IV paclitaxel (IVP) on progression-free survival (PFS) and on overall survival (OS), which supports superiority on the primary endpoint Overall Response Rate (ORR)." Moreover, "additional data presented highlight[ed] a favorable tolerability profile, as measured by continued low incidence of neuropathy as well as manageable gastrointestinal side effects."

155. The press release quotes Defendant Lau as explaining that "[h]aving previously presented superior efficacy on overall response rate and favorable tolerability versus IV paclitaxel at SABCS 2019, it is gratifying to report that our pivotal Phase 3 trial continues to show sustained efficacy and manageable adverse events with oral paclitaxel and encequidar."

156. The foregoing statements in ¶¶154-55 were materially false and misleading because, at the time they were made Defendants knew, or recklessly disregarded, but failed to disclose that:

(a) The Company's decision to pursue FDA approval for Oraxol via the abbreviated §505(b)(2) pathway without the FDA's prior authorization created a significant risk that the NDA would be rejected or that additional clinical studies would be required;

(b) Oraxol's NDA was at significant risk due to multiple undisclosed CMC changes that had been made during the Phase 3 Trial that disrupted the "comparability" between the prior data submitted in Oraxol's Phase 1 and 2 trials and the Phase 3 Trial;

(c) the protocols for the evaluation of Trial data injected the potential for bias into the BICR process and risked undermining the certainty of the data Athenex presented; and

(d) there was a significant risk that the FDA would recommend that a new clinical trial of patients representative of the U.S. population be conducted.

157. Defendants repeated substantially similar misstatements and omissions in a September 8, 2020 press release and presentation attached to a Form 8-K, in a special call with analysts that day, and in the Offering Documents issued in connection with the second SPO that began on September 10, 2020 (*supra*, ¶¶31, 88-90).

VII. LOSS CAUSATION

158. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic losses suffered by Plaintiff and members of the Class (defined herein). During the Class Period, Plaintiff and Class members purchased Athenex common stock at artificially inflated

prices caused by Defendants' misconduct. The price of the Company's common stock declined significantly when the substantial problems and risks misrepresented and concealed by Defendants materialized and/or were disclosed and Defendants' material misrepresentations and omissions were revealed to the market, causing investors' losses.

159. Throughout the Class Period, investors were unaware of the following material facts about Athenex that were known to Defendants throughout the Class Period:

(a) the Company's decision to pursue FDA approval for Oraxol via the abbreviated §505(b)(2) pathway without the FDA's prior authorization created a significant risk that the NDA would be rejected or that additional clinical studies would be required;

(b) Oraxol's NDA was at significant risk due to multiple undisclosed CMC changes that had been made during the Phase 3 Trial that disrupted the "comparability" between the prior data submitted in Oraxol's Phase 1 and 2 trials and the Phase 3 Trial;

(c) the protocols for the evaluation of Trial data injected the potential for bias into the BICR process and risked undermining the certainty of the data Athenex presented; and

(d) there was a significant risk that the FDA would recommend that a new clinical trial of patients representative of the U.S. population be conducted.

Following the revelation of the CRL and the multiple material misrepresentations and omissions, Athenex's common stock dropped from $12.10 per share at the close of the market on Friday, February 26, 2021, to $5.46 at the close of the market on Monday, March 1, 2021, a drop of approximately 55%.

160. The timing and magnitude of the decline in the price of Athenex's common stock, following the corrective disclosures as alleged herein and referenced above, negates any inference that the loss suffered by investors was caused by changed market conditions, macroeconomic or industry factors, or other facts unrelated to Defendants' fraudulent conduct. Defendants' false and misleading statements, as set forth above, proximately caused foreseeable losses to the members of the Class.

VIII. NO SAFE HARBOR

161. The federal statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pled herein, as the statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent any of the statements alleged to be false may be characterized as forward-looking, they were not identified as "forward-looking statements" when made and were unaccompanied by meaningful cautionary statements that identified important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

162. Alternatively, to the extent that the statutory safe harbor is found to apply to any forward-looking statements pleaded herein, Defendants are nonetheless liable for such statements because, at the time each such statements were made, the speaker had actual knowledge that it was materially false or misleading, and/or the statement was authorized or approved by an executive officer of Athenex who knew that the statements were materially false or misleading when made.

IX. CLASS ACTION ALLEGATIONS

163. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and 23(b)(3) on behalf of a Class consisting of all those who purchased or otherwise acquired shares of Athenex common stock between August 7, 2019 and February 26, 2021, inclusive (the "Class Period"), and were damaged thereby. Excluded from the Class are

Defendants, Athenex's current and former officers, directors, parents, and subsidiaries, their immediate family members, legal representatives, heirs, successors, or assigns of any such excluded person, and any entity in which Defendants have or had a controlling interest.

164. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Athenex common stock was actively traded on the Nasdaq. While the exact number of Class members is unknown to Plaintiff at this time, and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Stock holders and other members of the Class may be identified from records maintained by Athenex or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

165. Plaintiff's claims are typical of the claims of other Class members, as all members of the Class were similarly affected by Defendants' wrongful conduct in violation of federal laws as alleged herein.

166. Plaintiff will fairly and adequately protect Class members' interests and has retained competent counsel experienced in class actions and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

167. Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members. Common questions include:

(a) whether Defendants violated the federal securities laws as alleged herein;

(b) whether Defendants made public statements during the Class Period that were materially false, misleading, or incomplete or otherwise omitted material facts;

(c) whether the Individual Defendants caused Athenex to issue false and misleading statements;

(d) whether Defendants acted knowingly or recklessly in issuing false and misleading statements;

(e) whether the price of Athenex common stock during the Class Period was artificially inflated because of the Defendants' wrongful conduct as complained of herein; and

(f) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

168. A class action is superior to all other available methods for the fair and efficient adjudication of this action because joinder of all Class members is impracticable. Additionally, the damages suffered by some individual Class members may be relatively small so that the burden and expense of individual litigation make it impossible for them to individually redress the wrong done to them. There will be no difficulty in the management of this action as a class action.

169. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

(a) Defendants made public misrepresentations and failed to disclose material facts during the Class Period;

(b) the omissions and misrepresentations were material;

(c) Athenex's common stock is traded in an efficient market;

(d) Athenex's shares were liquid and traded with moderate to heavy volume during the Class Period;

(e) Athenex traded on the Nasdaq, which is a highly efficient stock market;

(f) Athenex was covered by multiple securities analysts;

(g) the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of Athenex's common stock; and

(h) Plaintiff and Class members purchased or acquired Athenex common stock without knowledge of the omitted or misrepresented facts.

170. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

171. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

X. CAUSES OF ACTION

COUNT ONE
Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder (Against All Defendants)

172. Plaintiff repeats and realleges each allegation contained above as if fully set forth herein. This claim is asserted on behalf of all members of the Class against Athenex and the Individual Defendants.

173. During the Class Period, Defendants, by their acts and omissions as alleged herein, carried out a plan, scheme, and course of conduct, which was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and the other Class members; (ii) artificially inflate and maintain the market price of Athenex common stock; and (iii) cause Plaintiff and Class members to purchase and hold Athenex common stock at artificially inflated prices.

174. Defendants: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the

statements not misleading; and (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of Athenex common stock in an effort to maintain artificially high market prices for shares of Athenex common stock in violation of §10(b) of the Exchange Act (15 U.S.C. §§78j(b)) and Rule 10b-5 promulgated thereunder. Defendants are sued as primary participants in the wrongful conduct charged herein.

175. Pursuant to the above plan, scheme, conspiracy, and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the materially false, misleading, and incomplete statements detailed above.

176. By virtue of their positions at Athenex, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein, and intended thereby to deceive Plaintiff and the other members of the Class; alternatively, Defendants acted with reckless disregard for the truth in that they recklessly failed to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, even though such facts were readily available to Defendants.

177. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As Athenex's senior officers and/or directors, the Individual Defendants had knowledge of the details of Athenex's internal affairs.

178. The Individual Defendants are liable, both directly and indirectly, for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to, and did, directly or indirectly, control the content of the statements of Athenex. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Athenex's businesses, operations, future financial condition, and future prospects. As a result of the

dissemination of the false and misleading reports, releases and public statements, the market price of Athenex common shares was artificially inflated throughout the Class Period. Unaware of the adverse facts concerning Athenex's business and financial condition, which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Athenex common shares at artificially inflated prices in reliance on the integrity of the market for such securities, and were damaged thereby.

179. During the Class Period, Athenex common stock traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, purchased or otherwise acquired shares of Athenex common stock at prices artificially inflated by Defendants' wrongful scheme and course of conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Athenex common stock was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Athenex common stock declined sharply upon public disclosure of the facts alleged herein, causing injury to Plaintiff and Class members. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for the shares of Athenex common stock that they purchased during the Class Period, which inflation was removed from its price as the true facts became known.

180. As a direct and proximate result of these Defendants' wrongful conduct, Plaintiff and the other members of the Class have suffered damages in connection with their purchases of Athenex common stock during the Class Period.

181. By reason of the conduct alleged herein, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

COUNT TWO
Violation of Section 20(a) of the Exchange Act
(Against the Individual Defendants)

182. Plaintiff repeats and realleges each allegation contained above as if fully set forth herein.

183. This Count is asserted on behalf of Plaintiff and all members of the Class against the Individual Defendants for violations of Section 20(a) of the Exchange Act ("Section 20(a)"), 15 U.S.C. §78t(a).

184. The Individual Defendants were and acted as controlling persons of Athenex within the meaning of Section 20(a), as alleged herein. By virtue of their high-level positions with the Company, participation in, and/or awareness of the Company's operations and/or intimate knowledge of the Company's actual performance, these Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. Each of these Defendants was provided with, or had unlimited access to, copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued, and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

185. In addition, the Individual Defendants had direct involvement in the day-to-day operations of the Company and, therefore, are presumed to have had the power to control or influence the transactions giving rise to the securities violations as alleged herein and exercised the same.

186. As set forth above, Athenex and the Individual Defendants each violated §10(b) and Rule 10b-5 by their acts and omissions as alleged in this Amended Complaint. By virtue of their control over Athenex, the Individual Defendants are also liable for Athenex's violation of Section 10(b) pursuant to Section 20(a).

XI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment as follows:

A. Declaring the action to be a proper class action pursuant to Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of the Class defined herein;

B. Awarding all damages and other remedies available under the Exchange Act in favor of Plaintiff and the members of the Class against Defendants in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including attorneys' fees and expert fees; and

D. Such other and further relief as the Court may deem just and proper.

XII. JURY DEMAND

Plaintiff demands a trial by jury.

DATED: November 19, 2021

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CERTIFICATE OF SERVICE

I hereby certify that on November 19, 2021, I caused the foregoing to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the email addresses denoted on the Electronic Mail Notice List.

/s/ Deborah Clark-Weintraub
DEBORAH CLARK-WEINTRAUB